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MEERUT (U.P.)
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Section 2f & 12B

IIMT College of Medical Sciences (Pharmacy)

ACADEMIC HAND BOOK

Ordinance & Academic Regulations

Diploma in Pharmacy

Pharmacy Council of India, New Delhi,
The Education Regulations, 2020 for Diploma Course in Pharmacy"
Syllabus framed under Regulation 7

1. Preamble

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

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

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

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

In this backdrop, the Council has formulated a Committee which comprised of 16 Members who have rich experiences in various domains such as education, hospital pharmacy practice, community pharmacy practice, clinical pharmacy practice, administrative and regulatory affairs to design the syllabus for the individual theory and practical courses as per the curriculum framework defined in ER-2020. The Committee with its clear understanding about the philosophy and objectives of the ER-2020, drafted the syllabus for individual theory and practical courses with utmost care to avoid repetitions, redundancy, over/under utilization of hours, etc. Every course is defined with scope, set of course objectives and course outcomes which will help to understand the significance and the expectations of the course from both teachers and students. Lots of scope has been given in the syllabus for the active learning by the students through the assignment topics and field visit activities which will enhance their

critical thinking, searching scientific literatures, interpretational skills and communication skills.

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

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

The Council strongly believes that the ER-2020 regulations, curriculum and syllabus will uplift the knowledge and skills of the students on par with the contemporary and future professional demands and enable them to be a successful practitioner in the chosen field of pharmacy.
By considering the substantial changes and inclusion of advanced and current subject matters in the new syllabus, the Council shall conduct series of meetings, seminars, conferences, workshops, and webinars for the faculty members handling D. Pharm courses and equip them to deliver such new courses / topics more effectively and efficiently.

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

2. Competencies for the Indian D. Pharm Holders

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

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

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

1. **Review Prescriptions:** The student should receive and handle prescriptions in a professional

manner and be able to check for their completeness and correctness. Also, the prescribers should be contacted for any clarifications and corrections in the prescriptions with suggestions if any.

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

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

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

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

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

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

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

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

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

3. Competency Mapping with the Courses (Part I, II & III) of Education Regulations 2020

4.

Competencies	Pharmaceutics	Pharmaceutical Chemistry	Pharmacognosy	Human Anatomy & Physiology	Social Pharmacy	Pharmacology	Community Pharmacy & Management	Biochemistry & Clinical Pathology	Pharmacotherapeutics	Hospital & Clinical Pharmacy	Pharmacy Law & Ethics	Practical Training
1. Review the Prescriptions	√	√	√	√		√	√	√	√	√	√	√
2. Dispense Prescription / Non-Prescription Medicines	√	√	√		√	√	√	√	√	√	√	√
3. Provide Patient Counselling / Education	√	√	√	√	√	√	√	√	√	√	√	√
4. Hospital and Community Pharmacy Management					√		√			√	√	√
5. Expertise on Medications	√	√	√	√	√	√	√	√	√	√	√	√
6. Proficiency on Pharmaceutical Formulations	√	√	√			√			√			√
7. Entrepreneurship and Leadership							√			√		√
8. Deliver Primary and Preventive Healthcare				√	√	√	√	√	√	√	√	√
9. Professional, Ethical and Legal Practice					√		√		√	√	√	√
10. Continuing Professional Development	√	√	√		√	√	√		√	√	√	√

5. ER-2020 D. Pharm Syllabus – An Overview

The ER-2020 D. Pharm Syllabus has the following structure in every course. Though the theory and practical courses are not mutually exclusive, as per the Regulations, the theory and practical are to be considered as individual courses.

Scope: These are broader statements on the purpose of the course in the curriculum, key contents of the course that will contribute to the specific knowledge and or skill developments. The teacher is expected to orient the students about the scope of the particular course at the beginning and intermittently.

Course Objectives: The course objectives describe the key topics that are intended by the teacher to be covered in the course. In general, these are more specific than the scope and broader than the course outcomes. The teacher is expected to discuss the objectives of the course with the students and break-down the course objectives into micro levels as objectives of a specific topic / objectives of a specific lecture, etc. Such an exercise shall make the students to understand the significance of the course / topic / lecture and enhance their attention on the course / topic / lecture.

Course Outcomes: The course outcomes are more specific than the course objectives describe that describe the abilities of the students to perform/act, upon successful completion of the course. Hence, conventionally the course outcomes are described with verbs that are measurable or observable actions. The teacher is expected to describe the desired outcomes of the particular course, so that the students shall understand the various assessment criteria, modalities, and parameters. This also serves as a broader guideline for the teachers for preparing the assessment plan. A well-structured assessment plan associated with the course outcomes shall enable to mapping with the professional competencies and their attainment levels that are attributed to the program outcomes.

Theory Courses: The theory courses basically provide concepts and explain the relationships between the concepts. Understanding of the theoretical courses enable the students to identify the problems in real life situation and make a plan for addressing such problems. Also, the theory course helps to understand what is not known and thus is the tool for accumulation of knowledge. The syllabus of the theory courses has been systematically and logically described as different chapters and the minimum number of hours to be spent on teaching are mentioned chapter wise and course wise. The teachers shall further distribute the total hours of any given chapter among the sub-topics as required by the subject matter.

Practical Courses: The practical courses are designed for applying the theoretical knowledge in the given experimental / simulated conditions. The practical courses deepen the understanding of theories, develop the skills, hone professional competencies, provide opportunities to observe, think and analyse problem solving methods. Further, they help to gain experience with the real things in practice. The teachers shall train the students in actual / simulated practical conditions.

Tutorials: The purpose of the tutorial hour is typically to engage the students in smaller groups in order to pay a closer attention on their learning process. This is an opportunity for the students to complete their assignments, develop specific skills, discuss any problems in the

study topics in a less formal way. During the tutorial hour, the students shall exchange their ideas within the small group, and learn to accept constructive criticism and listen to others. Also, the tutorial hour enables the teachers to closely monitor the progress of the individual student and provide additional academic support to individuals, if necessary.

Assignments: The purpose the assignments are to encourage the students for self- directed learning. Further, the assignments will provoke critical thinking, enhance the skills such as literature search, data mining, data interpretation, report formatting, time-management, and written communication. This is also a mode of self- assessment for the student about the level of understanding of the concepts of a particular course. The teachers shall apply their knowledge and wisdom in choosing the assignment topics at a micro level in alignment with the topics given in the syllabus. The assignments shall be evaluated against a set of criteria. A typical format for the assessment of an assignment is given in Appendix -1.

Field Visits: The purpose of field visits is to provide a real-world experience to the students. The field visits will help them to realize that what they learn within the walls of the classroom / laboratory can help them solve the problems they see in the world around them. Also, this is helpful to the teachers to widen their horizons of knowledge and broadening the scope of the syllabus. Every student shall submit a report describing their objectives, experience, learning points, etc. pertaining to the field trip, in the typical format given in Appendix-2.

Recommended Books: For each course, a list of recommended books is given in the syllabus. The list shall be considered as an important and common resource for the teaching-learning process, but not the complete list. It is always encouraged to use the latest edition of the books specified. Further, the teachers and students are encouraged to explore more primary, secondary, and tertiary resources as required.

Practical Training: The goal of the practical training for the students is to provide a real-time, supervised experience on the professional tasks emphasized in their course of study. Further, it helps them to apply their acquired knowledge and skills in the professional working environment. The practical training intensively prepares the students with adequate competencies and qualifications required for the career opportunity in the future.
Thus, the ER 2020 D. Pharm syllabus is designed to nurture the students in all the three domains of Bloom's Taxonomy viz. cognitive (knowledge), affective (attitude) and psychomotor (skills). Further, it also provides ample of scope to the students for different learning styles viz. visual, auditory and kinaesthetic, i.e., 'see, hear and do'.

The summary of the curriculum, courses and other activities and their metrics across the ER-2020 D. Pharm program (Part I, II & III) are given here.

Criteria	Metrics
Number of subject areas (considering both theory & practical together)	11
Number of theory courses	11
Number of practical courses	10
Number of theory hours	825
Number of practical hours	600
Number of practical training hours	500

Number of tutorial hours	275
Number of course outcomes for theory courses	45
Number of course outcomes for practical courses	40
Number of courses which have given assignments	9
Number of assignment topics given	75
Number of assignments reports each student shall submit	27
Number of courses which have field visit	5
Number of field visit reports each student shall submit	9
Number of professional competencies	10

6. Guidelines for the conduct of theory examinations

Sessional Examinations

There shall be two or more periodic sessional (internal assessment) examinations during each academic year. The duration of the sessional exam shall be 90 minutes. The highest aggregate of any two performances shall form the basis of calculating the sessional marks. The scheme of the question paper for theory sessional examinations shall be as given below.

I.	Long Answers (Answer 3 out of 4)	3 × 5 = 15
II.	Short Answers (Answer 5 out of 6)	5 × 3 = 15
III.	Objective type Answers (Answer all 10 out of 10) (Multiple Choice Questions / Fill-in the Blanks / One word OR one Sentence questions)	10 × 1 =10
	Total =	40 marks

Internal assessment: The marks secured by the students out of the total 40 shall be reduced to 20 in each sessional, and then the internal assessment shall be calculated based on the best two averages for 20 marks.

Final Board / University Examinations

The scheme of the question paper for the theory examinations conducted by the examining authority (Board / University) shall be as given below. The duration of the final examination shall be 3 hours.

I.	Long Answers (Answer 6 out of 7)	=	6 × 5 = 30
II.	Short Answers (Answer 10 out of 11)	=	10 × 3 = 30
III.	Objective type Answers (Answer all 20) (Multiple Choice Questions / Fill-in the Blanks / One word OR one Sentence questions)	=	20 × 1 = 20
	Total	=	80 marks

7. Guidelines for the conduct of practical examinations

Sessional Examinations

There shall be two or more periodic sessional (internal assessment) practical examinations during each academic year. The duration of the sessional exam shall be three hours. The highest aggregate of any two performances shall form the basis of calculating the sessional marks. The scheme of the question paper for practical sessional examinations shall be as given below.

I.	Synopsis	=	10
II.	Experiments	=	50*
III.	Viva voce	=	10
IV.	Practical Record Maintenance	=	10
		Total =	80 marks

* The marks for the experiments shall be divided into various categories, viz. major experiment, minor experiment, spotters, etc. as per the requirement of the course.

Internal assessment: The marks secured by the students out of the total of 80 shall be reduced to 10 in each sessional, and then the internal assessment shall be calculated based on the best two averages for 10 marks from the sessional and other 10 marks shall be awarded as per the details given below.

Actual performance in the sessional examination	=
10 marks Assignment marks (Average of three)	= 5 marks* Field Visit Report marks
(Average for the reports)	= 5 marks$
Total	= 20 marks

Note: *, $ Only for the courses given with both assignments and field visit/s

1. For the courses having either assignments or field visit/s, the assessments of assignments or field visit/s shall be done directly for 10 marks and added to the sessional marks.

2. For the courses not having both assignment and field visit, the whole 20 marks shall be calculated from the sessional marks.

Final Board / University Examinations

The scheme of the question paper for the practical examinations conducted by the examining authority (Board / University) shall be as given below. The duration of the final examination shall be 3 hours.

I. Synopsis = 10

II. Experiments = 60*
III. Viva voce = 10
Total = **80 marks**

* The marks for the experiments shall be divided into various categories, viz. major experiment, minor experiment, spotters, etc. as per the requirement of the course.

8. ER-2020 D. Pharm Syllabus – Part I

S. No.	Course Code	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week
1.	ER20-11T	Pharmaceutics–Theory	75	25	3	1
2.	ER20-11P	Pharmaceutics–Practical	75	-	3	-
3.	ER20-12T	Pharmaceutical Chemistry – Theory	75	25	3	1
4.	ER20-12P	Pharmaceutical Chemistry – Practical	75	-	3	-
5.	ER20-13T	Pharmacognosy–Theory	75	25	3	1
6.	ER20-13P	Pharmacognosy–Practical	75	-	3	-
7.	ER20-14T	Human Anatomy & Physiology–Theory	75	25	3	1
8.	ER20-14P	Human Anatomy & Physiology – Practical	75	-	3	-
9.	ER20-15T	Social Pharmacy–Theory	75	25	3	1
10.	ER20-15P	Social Pharmacy–Practical	75	-	3	-

PHARMACEUTICS – THEORY

Course Code: ER20-11T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge and skills on the art and science of formulating and dispensing different pharmaceutical dosage forms.

Course Objectives: This course will discuss the following aspects of pharmaceutical dosage forms

1. Basic concepts, types and need
2. Advantages and disadvantages, methods of preparation / formulation
3. Packaging and labelling requirements
4. Basic quality control tests, concepts of quality assurance and good manufacturing practices

Course Outcomes: Upon successful completion of this course, the students will be able to
1. Describe about the different dosage forms and their formulation aspects
2. Explain the advantages, disadvantages, and quality control tests of different dosage forms
3. Discuss the importance of quality assurance and good manufacturing practices

Chapter	Topics	Hours
1	• **History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations.** • **Pharmacy as a career** • **Pharmacopoeia: Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia**	7
2	**Packaging materials: Types, selection criteria, advantages and disadvantages of glass, plastic, metal,** **rubber as packaging materials**	5
3	**Pharmaceutical aids: Organoleptic (Colouring, flavouring, and sweetening) agents** **Preservatives: Definition, types with examples and uses**	3
4	**Unit operations: Definition, objectives/applications, principles, construction, and workings of:** **Size reduction: hammer mill and ball mill** **Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves** **Mixing:** Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer **Filtration:** Theory of filtration, membrane filter and sintered glass filter **Drying:** working of fluidized bed dryer and process of freeze drying **Extraction:** Definition, Classification, method and applications	9
5	**Tablets** – coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi- layered, etc.) **Capsules** - hard and soft gelatin capsules **Liquid oral preparations** - solution, syrup, elixir, emulsion, suspension, dry	**8** **4** **6**

	powder for reconstitution **Topical preparations** - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries Nasal preparations, Ear preparations **Powders and granules** - Insufflations, dusting powders, effervescent powders, and effervescent granules **Sterile formulations** – Injectable, eye drops and eye ointments **Immunological products**: Sera, vaccines, toxoids, and their manufacturing methods.	**8** **2** **3** **6** **4**
6	**Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants Quality control and quality assurance**: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation	**5**
7	**Novel drug delivery systems:** Introduction, Classification with examples, advantages, and challenges	**5**

PHARMACEUTICS – PRACTICAL

Course Code: ER20-11P **75 Hours (3 Hours/week)**

Scope: This course is designed to train the students in formulating and dispensing common pharmaceutical dosage forms.

Course Objectives: This course will discuss and train the following aspects of preparing and dispensing various pharmaceutical dosage forms

1. Calculation of working formula from the official master formula
2. Formulation of dosage forms based on working formula
3. Appropriate Packaging and labelling requirements
4. Methods of basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to
1. Calculate the working formula from the given master formula
2. Formulate the dosage form and dispense in an appropriate container
3. Design the label with the necessary product and patient information
4. Perform the basic quality control tests for the common dosage forms

Practical's

1. Handling and referring the official references: Pharmacopoeias, Formularies, etc. for retrieving formulas, procedures, etc.

2. Formulation of the following dosage forms as per monograph standards and dispensing with appropriate packaging and labeling

    - **Liquid Oral:** Simple syrup, Piperazine citrate elixir, Aqueous Iodine solution
    - **Emulsion:** Castor oil emulsion, Cod liver oil emulsion
    - **Suspension:** Calamine lotion, Magnesium hydroxide mixture
    - **Ointment:** Simple ointment base, Sulphur ointment
    - **Cream:** Cetrimide cream
    - **Gel:** Sodium alginate gel
    - **Liniment:** Turpentine liniment, White liniment BPC
    - **Dry powder:** Effervescent powder granules, Dusting powder
    - **Sterile Injection:** Normal Saline, Calcium gluconate Injection
    - **Hard Gelatine Capsule:** Tetracycline capsules
    - **Tablet:** Paracetamol tablets

3. Formulation of at least five commonly used cosmetic preparations – e.g. cold cream, shampoo, lotion, toothpaste etc

4. Demonstration on various stages of tablet manufacturing processes

5. Appropriate methods of usage and storage of all dosage forms including special dosage such as different types of inhalers, spacers, insulin pens

6. Demonstration of quality control tests and evaluation of common dosage forms viz. tablets, capsules, emulsion, sterile injections as per the monographs

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Various systems of measures commonly used in prescribing, compounding and dispensing practices

2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, their generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical

3. Overview of various machines / equipment~~'s~~ / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.

4. Overview of extemporaneous preparations at community / hospital pharmacy vs. manufacturing of dosage forms at industrial level

5. Basic pharmaceutical calculations: ratios, conversion to percentage fraction, allegation, proof spirit, isotonicity.

Field Visit

The students shall be taken for an industrial visit to pharmaceutical industries to witness and understand the various processes of manufacturing of any of the common dosage forms viz. tablets, capsules, liquid orals, injectable, etc. Individual reports from each student on their learning experience from the field visit shall be submitted.

PHARMACEUTICAL CHEMISTRY – THEORY

Course Code: ER20-12T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on the chemical structure, storage conditions and medicinal uses of organic and inorganic chemical substances used as drugs and pharmaceuticals. Also, this course discusses the impurities, quality control aspects of chemical substances used in pharmaceuticals.

Course Objectives: This course will discuss the following aspects of the chemical substances used as drugs and pharmaceuticals for various disease conditions

1. Chemical classification, chemical name, chemical structure
2. Pharmacological uses, doses, stability and storage conditions
3. Different types of formulations / dosage form available and their brand names
4. Impurity testing and basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the chemical class, structure and chemical name of the commonly used drugs and pharmaceuticals of both organic and inorganic nature
2. Discuss the pharmacological uses, dosage regimen, stability issues and storage conditions of all such chemical substances commonly used as drugs
3. Describe the quantitative and qualitative analysis, impurity testing of the chemical substances given in the official monographs
4. Identify the dosage form & the brand names of the drugs and pharmaceuticals popular in the marketplace

Chapter	Topic	Hours
1	**Introduction to Pharmaceutical chemistry:** Scope and objectives **Sources and types of errors:** Accuracy, precision, significant figures **Impurities in Pharmaceuticals**: Source and effect of impurities in Pharmacopoeial substances, importance of limit test, Principle and procedures of Limit tests for chlorides, sulphates, iron, heavy metals and arsenic.	8
2	**Volumetric analysis**: Fundamentals of volumetric analysis, Acid-base titration, non-aqueous titration, precipitation titration, complex metric titration, redox titration **Gravimetric analysis:** Principle and method.	8
3	**Inorganic Pharmaceuticals**: Pharmaceutical formulations, market preparations, storage conditions and uses of ● **Haematinics:** Ferrous sulphate, Ferrous fumarate, Ferric ammonium citrate, Ferrous ascorbate, Carbonyl iron ● **Gastro-intestinal Agents:** Antacids : Aluminium hydroxide gel, Magnesium hydroxide, Magaldrate, Sodium bicarbonate, Calcium Carbonate, Acidifying agents, Adsorbents, Protectives, Cathartics ● **Topical agents:** Silver Nitrate, Ionic Silver, Chlorhexidine Gluconate, Hydrogen peroxide, Boric acid, Bleaching powder, Potassium	7

	permanganate ● **Dental products:** Calcium carbonate, Sodium fluoride, Denture cleaners, Denture adhesives, Mouth washes ● **Medicinal gases:** Carbon dioxide, nitrous oxide, oxygen	
4	Introduction to nomenclature of organic chemical systems with particular reference to heterocyclic compounds containing up to Three rings	**2**
Study of the following category of medicinal compounds with respect to classification, chemical name, chemical structure (compounds marked with*) uses, stability and storage conditions, different types of formulations and their popular brand names		
5	**Drugs Acting on Central Nervous System** ● **Anaesthetics:** Thiopental Sodium*, Ketamine Hydrochloride*, Propofol ● **Sedatives and Hypnotics:** Diazepam*, Alprazolam*, Nitrazepam, Phenobarbital* ● **Antipsychotics:** Chlorpromazine Hydrochloride*, Haloperidol*, Risperidone*, Sulpiride*, Olanzapine, Quetiapine, Lurasidone ● **Anticonvulsants:** Phenytoin*, Carbamazepine*, Clonazepam, Valproic Acid*, Gabapentin*, Topiramate, Vigabatrin, Lamotrigine ● **Anti-Depressants:** Amitriptyline Hydrochloride*, Imipramine Hydrochloride*, Fluoxetine*, Venlafaxine, Duloxetine, Sertraline, Citalopram, Escitalopram, Fluvoxamine, Paroxetine	**9**
6	**Drugs Acting on Autonomic Nervous System** **Sympathomimetic Agents:** ***Direct Acting:*** Nor-Epinephrine*, Epinephrine, Phenylephrine, Dopamine*, Terbutaline, Salbutamol (Albuterol), Naphazoline*, Tetrahydrozoline. ***Indirect Acting Agents:*** Hydroxy Amphetamine, Pseudoephedrine. Agents With Mixed Mechanism**:** Ephedrine, Metaraminol ● **Adrenergic Antagonists:** Alpha Adrenergic Blockers: Tolazoline, Phentolamine ● Phenoxybenzamine, Prazosin. Beta Adrenergic Blockers: Propranolol*, Atenolol*, Carvedilol ● **Cholinergic Drugs and Related Agents:** Direct Acting Agents: Acetylcholine*, Carbachol, and Pilocarpine. Cholinesterase Inhibitors: Neostigmine*, Edrophonium Chloride, Tacrine Hydrochloride, Pralidoxime Chloride, Echothiopate Iodide ● **Cholinergic Blocking Agents:** Atropine Sulphate*, Ipratropium Bromide ***Synthetic Cholinergic Blocking Agents***: Tropicamide, Cyclopentolate Hydrochloride, Clidinium Bromide, Dicyclomine Hydrochloride*	**9**
7	**Drugs Acting on Cardiovascular System** ● **Anti-Arrhythmic Drugs**: Quinidine Sulphate, Procainamide Hydrochloride, Verapamil, Phenytoin Sodium*, Lidocaine Hydrochloride, Lorcainide Hydrochloride, Amiodarone and Sotalol ● **Anti-Hypertensive Agents**: Propranolol*, Captopril*, Ramipril, Methyldopate Hydrochloride, Clonidine Hydrochloride, Hydralazine Hydrochloride, Nifedipine, ● **Antianginal Agents**: Isosorbide Dinitrate	**5**
8	**Diuretics:** Acetazolamide, Frusemide*, Bumetanide, Chlorthalidone, Benzthiazide, Metolazone, Xipamide, Spironolactone	**2**

9	**Hypoglycemic Agents:** Insulin and Its Preparations, Metformin*, Glibenclamide*, Glimepiride, Pioglitazone, Repaglinide, Gliflozins, Gliptins	**3**
10	**Analgesic And Anti-Inflammatory Agents:** Morphine Analogues, Narcotic Antagonists; ***Nonsteroidal Anti- Inflammatory Agents (NSAIDs)*** - Aspirin*, Diclofenac, Ibuprofen*, Piroxicam, Celecoxib, Mefenamic Acid, Paracetamol*, Aceclofenac	**3**
11	**Anti-Infective Agents** ● **Antifungal Agents:** Amphotericin-B, Griseofulvin, Miconazole, Ketoconazole*, Itraconazole, Fluconazole*, Naftifine Hydrochloride	**8**
	● **Urinary Tract Anti-Infective Agents:** Norfloxacin, Ciprofloxacin, Ofloxacin*, Moxifloxacin, ● **Anti-Tubercular Agents:** INH*, Ethambutol, Para Amino Salicylic Acid, Pyrazinamide, Rifampicin, Bedaquiline, Delamanid, Pretomanid* ● **Antiviral Agents:** Amantadine Hydrochloride, Idoxuridine, Acyclovir*, Foscarnet, Zidovudine, Ribavirin, Remdesivir, Favipiravir ● **Antimalarials:** Quinine Sulphate, Chloroquine Phosphate*, Primaquine Phosphate, Mefloquine*, Cycloguanil, Pyrimethamine, Artemisinin ● **Sulfonamides:** Sulfanilamide, Sulfadiazine, Sulfametho xazole, Sulfacetamide*, Mafenide Acetate, Cotrimoxazole, Dapsone*	
12	**Antibiotics:** Penicillin G, Amoxicillin*, Cloxacillin, Streptomycin, ***Tetracyclines:*** Doxycycline, Minocycline, ***Macrolides:*** Erythromycin, Azithromycin, ***Miscellaneous:*** Chloramphenicol* Clindamycin	**8**
13	**Anti-Neoplastic Agents:** Cyclophosphamide*, Busulfan, Mercaptopurine, Fluorouracil*, Methotrexate, Dactinomycin, Doxorubicin Hydrochloride, Vinblastine Sulphate, Cisplatin*, Dromostanolone Propionate	**3**

PHARMACEUTICAL CHEMISTRY – PRACTICAL

Course Code: ER20-12P **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic training and hands-on experiences to synthesis chemical substances used as drugs and pharmaceuticals. Also, to perform the quality control tests, impurity testing, test for purity and systematic qualitative analysis of chemical substances used as drugs and pharmaceuticals.

Course Objectives: This course will provide the hands-on experience on the following aspects of chemical substances used as drugs and pharmaceuticals

1. Limit tests and assays of selected chemical substances as per the monograph
2. Volumetric analysis of the chemical substances
3. Basics of preparatory chemistry and their analysis
4. Systematic qualitative analysis for the identification of the chemical drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Perform the limit tests for various inorganic elements and report
2. Prepare standard solutions using the principles of volumetric analysis
3. Test the purity of the selected inorganic and organic compounds against the monograph standards
4. Synthesize the selected chemical substances as per the standard synthetic scheme
5. Perform qualitative tests to systematically identify the unknown chemical substances

Practical

S. No.	Experiment
1	**Limit test for** ● Chlorides; sulphate; Iron; heavy metals
2	Identification tests for Anions and Cations as per Indian Pharmacopoeia
3	**Fundamentals of Volumetric analysis** Preparation of standard solution and standardization of Sodium Hydroxide, Potassium Permanganate
4	**Assay of the following compounds** ● Ferrous sulphate- by redox titration ● Calcium gluconate-by complexometric ● Sodium chloride-by Modified Volhard's method ● Ascorbic acid by iodometry ● Ibuprofen by alkalimetry
5	**Fundamentals of preparative organic chemistry** Determination of Melting point and boiling point of organic compounds
6	**Preparation of organic compounds** • Benzoic acid from Benzamide • Picric acid from Phenol
7	**Identification and test for purity of pharmaceuticals**

	Aspirin, Caffeine, Paracetamol, Sulfanilamide
8	Systematic Qualitative analysis experiments (4 substances)

Assignments

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Different monographs and formularies available and their major contents
2. Significance of quality control and quality assurance in pharmaceutical industries
3. Overview on Green Chemistry
4. Various software programs available for computer aided drug discovery
5. Various instrumentations used for characterization and quantification of drug

PHARMACOGNOSY – THEORY

Course Code: ER20-13T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart knowledge on the medicinal uses of various drugs of natural origin. Also, the course emphasizes the fundamental concepts in the evaluation of crude drugs, alternative systems of medicine, nutraceuticals, and herbal cosmetics.

Course Objectives: This course will discuss the following aspects of drug substances derived from natural resources.

1. Occurrence, distribution, isolation, identification tests of common phyto-constituents
2. Therapeutic activity and pharmaceutical applications of various natural drug substances and phyto-constituents
3. Biological source, chemical constituents of selected crude drugs and their therapeutic efficacy in common diseases and ailments
4. Basic concepts in quality control of crude drugs and various system of medicines
5. Applications of herbs in health foods and cosmetics
6.

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Identify the important/common crude drugs of natural origin
2. Describe the uses of herbs in nutraceuticals and cosmeceuticals
3. Discuss the principles of alternative system of medicines
4. Describe the importance of quality control of drugs of natural origin
5.

Chapter	Topic	Hours
1	Definition, history, present status and scope of Pharmacognosy	2
2	**Classification of drugs:** ● Alphabetical ● Taxonomical ● Morphological ● Pharmacological ● Chemical ● Chemo-taxonomical	4
3	**Quality control of crude drugs:** ● Different methods of adulteration of crude drugs ● Evaluation of crude drugs	6
4	Brief outline of occurrence, distribution, isolation, identification tests, therapeutic activity and pharmaceutical applications of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.	6

5	Biological source, chemical constituents and therapeutic efficacy of the following categories of crude drugs.		**30**
	Laxatives	Aloe, Castor oil, Ispaghula, Senna	
	Cardiotonic	Digitalis, Arjuna	
	Carminatives and G.I. regulators	Coriander, Fennel, Cardamom, Ginger, Clove, Black Pepper, Asafoetida, Nutmeg, Cinnamon	
	Astringents	Myrobalan, Black Catechu, Pale Catechu	
	Drugs acting on nervous system	Hyoscyamus, Belladonna, Ephedra, Opium, Tea leaves, Coffee seeds, Coca	
	Anti-hypertensive	Rauwolfia	
	Anti-tussive	Vasaka, Tolu Balsam	
	Anti-rheumatics	Colchicum seed	
	Anti-tumour	Vinca, Podophyllum	
	Antidiabetics	Pterocarpus, Gymnema	
	Diuretics	Gokhru, Punarnava	
	Anti-dysenteric	Ipecacuanha	
	Antiseptics and disinfectants	Benzoin, Myrrh, Neem, Turmeric	
	Antimalarials	Cinchona, Artemisia	
	Oxytocic	Ergot	
	Vitamins	Cod liver oil, Shark liver oil	
	Enzymes	Papaya, Diastase, Pancreatin, Yeast	
	Pharmaceutical Aids	Kaolin, Lanolin, Beeswax, Acacia, Tragacanth, Sodium alginate, Agar, Guar gum, Gelatine	
	Miscellaneous	Squill, Galls, Ashwagandha, Tulsi, Guggul	
6	**Plant fibres used as surgical dressings:** Cotton, silk, wool and regenerated fibres Sutures – Surgical Catgut and Ligatures		**3**
7	• **Basic principles involved in the traditional systems of medicine like:** Ayurveda, Siddha, Unani and Homeopathy • **Method of preparation of Ayurvedic formulations like:** Arista, Asava, Gutika, Taila, Churna, Lehya and Bhasma		**8**
8	Role of medicinal and aromatic plants in national economy and their export potential		**2**
9	**Herbs as health food:** Brief introduction and therapeutic applications of: Nutraceuticals, Antioxidants, Pro-biotics, Pre-biotics, Dietary fibres, Omega-3-fatty acids, Spirulina, Carotenoids, Soya and Garlic		**4**
10	Introduction to herbal formulations		**4**
11	**Herbal cosmetics:** Sources, chemical constituents, commercial preparations, therapeutic and cosmetic uses of: Aloe vera gel, Almond oil, Lavender oil, Olive oil, Rosemary oil, Sandal Wood oil		**4**
12	Phytochemical investigation of drugs		**2**

PHARMACOGNOSY – PRACTICAL

Course Code: ER20-13P **75 Hours (3 Hours/week)**

Scope: This course is designed to train the students in physical identification, morphological characterization, physical and chemical characterization, and evaluation of commonly used herbal drugs.

Course Objectives: This course will provide hands-on experiences to the students in

1. Identification of the crude drugs based on their morphological characteristics
2. Various characteristic anatomical characteristics of the herbal drugs studied through transverse section
3. Physical and chemical tests to evaluate the crude drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Identify the given crude drugs based on the morphological characteristics
2. Take a transverse section of the given crude drugs
3. Describe the anatomical characteristics of the given crude drug under microscopical conditions
4. Carry out the physical and chemical tests to evaluate the given crude drugs

Practicals

1. **Morphological Identification of the following drugs:**
   Ispaghula, Senna, Coriander, Fennel, Cardamom, Ginger, Nutmeg, Black Pepper, Cinnamon, Clove, Ephedra, Rauwolfia, Gokhru, Punarnava, Cinchona, Agar.
2. **Gross anatomical studies (Transverse Section) of the following drugs:** Ajwain, Datura, Cinnamon, Cinchona, Coriander, Ashwagandha, Liquorice, Clove, Curcuma, Nux vomica, Vasaka
3. **Physical and chemical tests for evaluation of any FIVE of the following drugs:**
   Asafoetida, Benzoin, Pale catechu, Black catechu, Castor oil, Acacia, Tragacanth, Agar, Guar gum, Gelatin.

Assignments

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Market preparations of various dosage forms of Ayurvedic, Unani, Siddha, Homeopathic (Classical and Proprietary), indications, and their labelling requirements
2. Market preparations of various herbal formulations and herbal cosmetics, indications, and their labelling requirements
3. Herb-Drug interactions documented in the literature and their clinical significances

Field Visit

The students shall be taken in groups to a medicinal garden to witness and understand the nature of various medicinal plants discussed in theory and practical courses. Additionally, they shall be taken in groups to the pharmacies of traditional systems of medicines to understand the availability of various dosage forms and their labelling requirements. Individual reports from each student on their learning experience from the field visit shall be submitted.

HUMAN ANATOMY AND PHYSIOLOGY – THEORY

Course Code: ER20-14T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on the structure and functions of the human body. It helps in understanding both homeostasis mechanisms and homeostatic imbalances of various systems of the human body.

Course Objectives: This course will discuss the following:
1. Structure and functions of the various organ systems and organs of the human body
2. Homeostatic mechanisms and their imbalances in the human body
3. Various vital physiological parameters of the humanbody and their significances

Course Outcomes: Upon successful completion of this course, the students will be able to
1. Describe the various organ systems of the human body
2. Discuss the anatomical features of the important human organs and tissues
3. Explain the homeostatic mechanisms regulating the normal physiology in the human system
4. Discuss the significance of various vital physiological parameters of the human body

Chapter	Topic	Hours
1	Scope of Anatomy and Physiology Definition of various terminologies	2
2	**Structure of Cell**: Components and its functions	2
3	**Tissues of the human body**: Epithelial, Connective, Muscular and Nervous tissues – their sub - types and characteristics.	4
4	**Osseous system**: structure and functions of bones of axial and appendicular skeleton Classification, types and movements of joints, disorders of joints	3
5	**Haemopoietic system** ● Composition and functions of blood ● Process of Hemopoiesis ● Characteristics and functions of RBCs, WBCs, and platelets ● Mechanism of Blood Clotting ● Importance of Blood groups	8
	Lymphatic system ● Lymph and lymphatic system, composition, function and its formation. ● Structure and functions of spleen and lymph node.	3
7	**Cardiovascular system** ● Anatomy and Physiology of heart ● Blood vessels and circulation (Pulmonary, coronary and systemic circulation) ● Cardiac cycle and Heart sounds, Basics of ECG ● Blood pressure and its regulation	8
8	**Respiratory system** ● Anatomy of respiratory organs and their functions. ● Regulation, and Mechanism of respiration. ● Respiratory volumes and capacities – definitions	4

9	**Digestive system** ● Anatomy and Physiology of the GIT ● Anatomy and functions of accessory glands ● Physiology of digestion and absorption	**8**
10	**Skeletal muscles** ● Histology ● Physiology of muscle contraction ● Disorder of skeletal muscles	**2**
11	**Nervous system** ● Classification of nervous system ● Anatomy and physiology of cerebrum, cerebellum, mid brain ● Function of hypothalamus, medulla oblongata and basal ganglia ● Spinal cord-structure and reflexes ● Names and functions of cranial nerves. ● Anatomy and physiology of sympathetic and parasympathetic nervous system (ANS)	**8**
12	**Sense organs - Anatomy and physiology of** ● Eye ● Ear ● Skin ● Tongue ● Nose	**6**
13	**Urinary system** ● Anatomy and physiology of urinary system ● Physiology of urine formation ● Renin - angiotensin system ● Clearance tests and micturition	**4**
14	**Endocrine system (Hormones and their functions)** ● Pituitary gland ● Adrenal gland ● Thyroid and parathyroid gland ● Pancreas and gonads	**6**
15	**Reproductive system** ● Anatomy of male and female reproductive system ● Physiology of menstruation ● Spermatogenesis and Oogenesis ● Pregnancy and parturition	**4**

HUMAN ANATOMY AND PHYSIOLOGY – PRACTICAL

Course Code: ER20-14P **75 Hours (3 Hours/week)**

Scope: This course is designed to train the students and instill the skills for carrying out basic physiological monitoring of various systems and functions.

Course Objectives: This course will provide hands-on experience in the following:

1. General blood collection techniques and carrying out various haematological assessments and interpreting the results
2. Recording and monitoring the vital physiological parameters in human subjects and the basic interpretations of the results
3. Microscopic examinations of the various tissues permanently mounted in glass slides
4. Discuss the anatomical and physiological characteristics of various organ systems of the body using models, charts, and other teaching aids

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Perform the haematological tests in human subjects and interpret the results
2. Record, monitor and document the vital physiological parameters of human subjects and interpret the results
3. Describe the anatomical features of the important human tissues under the microscopical conditions
4. Discuss the significance of various anatomical and physiological characteristics of the human body

Practical

1. Study of compound microscope
2. General techniques for the collection of blood
3. Microscopic examination of epithelial tissue, Cardiac muscle, Smooth muscle, Skeletal muscle, Connective tissue, and Nervous tissue of ready / pre-prepared slides.
4. Study of Human Skeleton-Axial skeleton and appendicular skeleton
5. Determination of
   a. Blood group
   b. ESR
   c. Hemoglobin content of blood
   d. Bleeding time and Clotting time
6. Determination of WBC count of blood
7. Determination of RBC count of blood
8. Determination of Differential count of blood
9. Recording of Blood Pressure in various postures, different arms, before and after exertion and interpreting the results
10. Recording of Body temperature (using mercury, digital and IR thermometers at various locations), Pulse rate/ Heart rate (at various locations in the body, before and after exertion), Respiratory Rate
11. Recording Pulse Oxygen (before and after exertion)
12. Recording force of air expelled using Peak Flow Meter
13. Measurement of height, weight, and BMI
14. Study of various systems and organs with the help of chart, models, and specimens

a) Cardiovascular system
b) Respiratory system
c) Digestive system
d) Urinary system
e) Endocrine system
f) Reproductive system
g) Nervous system
h) Eye
i) Ear
j) Skin

SOCIAL PHARMACY – THEORY

Course Code: ER20-15T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on public health, epidemiology, preventive care, and other social health related concepts. Also, to emphasize the roles of pharmacists in the public health programs.

Course Objectives: This course will discuss about basic concepts of

1. Public health and national health programs
2. Preventive healthcare
3. Food and nutrition related health issues
4. Health education and health promotion
5. General roles and responsibilities of pharmacists in public health

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Discuss about roles of pharmacists in the various national health programs.
2. Describe various sources of health hazards and disease preventive measures.
3. Discuss the healthcare issues associated with food and nutritional substances.
4. Describe the general roles and responsibilities of pharmacists in public health.

Chapter	Topic	Hours
1	**Introduction to Social Pharmacy** • Definition and Scope. Social Pharmacy as a discipline and its scope in improving the public health. Role of Pharmacists in Public Health. (2) • Concept of Health -WHO Definition, various dimensions, determinants, and health indicators. (3) • National Health Policy – Indian perspective (1) • Public and Private Health System in India, National Health Mission (2) • Introduction to Millennium Development Goals, Sustainable Development Goals, FIP Development Goals (1)	9
2	**Preventive healthcare – Role of Pharmacists in the following** • Demography and Family Planning (3) • Mother and child health, importance of breastfeeding, ill effects of infant milk substitutes and bottle feeding (2) • Overview of Vaccines, types of immunity and immunization (4)	18
	• Effect of Environment on Health – Water pollution, importance of safe drinking water, waterborne diseases, air pollution, noise pollution, sewage and solid waste disposal, occupational illnesses, Environmental pollution due to pharmaceuticals (7) • Psychosocial Pharmacy: Drugs of misuse and abuse – psychotropics, narcotics, alcohol, tobacco products. Social Impact of these habits on social health and productivity and suicidal behaviours (2)	
3	**Nutrition and Health** • Basics of nutrition–Macronutrients and Micronutrients (3) • Importance of water and fibres in diet (1) • Balanced diet, Malnutrition, nutrition deficiency diseases, ill effects of	10

	junk foods, calorific and nutritive values of various foods, fortification of food (3) • Introduction to food safety, adulteration of foods, effects of artificial ripening, use of pesticides, genetically modified foods (1) • Dietary supplements, nutraceuticals, food supplements – indications, benefits, Drug-Food Interactions (2)	
4	Introduction to Microbiology and common microorganisms (3) **Epidemiology:** Introduction to epidemiology, and its applications. Understanding of terms such as epidemic, pandemic, endemic, mode of transmission, outbreak, quarantine, isolation, incubation period, contact tracing, morbidity, mortality, . (2) Causative agents, epidemiology and clinical presentations and Role of Pharmacists in educating the public in prevention of the following communicable diseases: • Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1, SARS, MERS, COVID-19), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis, Ebola (7) • Intestinal infections – poliomyelitis, viral hepatitis, cholera, acute diarrheal diseases, typhoid, amebiasis, worm infestations, food poisoning (7) • Arthropod-borne infections - dengue, malaria, filariasis and, chikungunya (4) • Surface infections – trachoma, tetanus, leprosy (2) • STDs, HIV/AIDS (3)	**28**
5	Introduction to health systems and **all ongoing National Health programs** in India, their objectives, functioning, outcome, and the role of pharmacists.	**8**
6	**Pharmacoeconomics** – Introduction, basic terminologies, importance of pharmacoeconomics	**2**

SOCIAL PHARMACY – PRACTICAL

Course Code: ER20-15P **75 Hours (3 Hours/week)**

Scope: This course is designed to provide simulated experience in various public health and social pharmacy activities.

Course Objectives: This course will train the students on various roles of pharmacists in public health and social pharmacy activities in the following areas:

1. National immunization programs
2. Reproductive and child health programs
3. Food and nutrition related health programs
4. Health education and promotion
5. General roles and responsibilities of the pharmacists in public health
6. First Aid for various emergency conditions including basic life support and cardiopulmonary resuscitation

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the roles and responsibilities of pharmacists in various National health programs
2. Design promotional materials for public health awareness
3. Describe various health hazards including microbial sources
4. Advice on preventive measures for various diseases
5. Provide first aid for various emergency conditions

Note: Demonstration / Hands-on experience / preparation of charts / models / promotional materials / role plays / enacting / e-brochures / e-flyers / podcasts / video podcasts / any other innovative activities to understand the concept of various elements of social pharmacy listed here. (At least one activity to be carried out for each one of the following):

Practicals

1. National immunization schedule for children, adult vaccine schedule, Vaccines which are not included in the National Immunization Program.
2. RCH – reproductive and child health – nutritional aspects, relevant national health programmes.
3. Family planning devices
4. Microscopical observation of different microbes (readymade slides)
5. Oral Health and Hygiene
6. Personal hygiene and etiquettes – hand washing techniques, Cough and sneeze etiquettes.
7. Various types of masks, PPE gear, wearing/using them, and disposal.
8. Menstrual hygiene, products used
9. First Aid – Theory, basics, demonstration, hands on training, audio-visuals, and practice, BSL (Basic Life Support) Systems [SCA - Sudden Cardiac Arrest, FBAO - Foreign Body Airway Obstruction, CPR, Defibrillation (using AED) (Includes CPR techniques, First Responder).
10. Emergency treatment for all medical emergency cases viz. snake bite, dog bite, insecticide poisoning, fractures, burns, epilepsy etc.
11. Role of Pharmacist in Disaster Management.
12. Marketed preparations of disinfectants, antiseptics, fumigating agents, antilarval agents, mosquito repellents, etc.
13. Health Communication: Audio / Video podcasts, Images, Power Point Slides, Short Films, etc. in regional language(s) for mass communication / education / Awareness on 5 different communicable diseases, their signs and symptoms, and prevention.

14. Water purification techniques, use of water testing kit, calculation of Content/percentage of KMnO4, bleaching powder to be used for wells/tanks
15. Counselling children on junk foods, balanced diets – using Information, Education and Communication (IEC), counselling, etc. (Simulation Experiments).
16. Preparation of various charts on nutrition, sources of various nutrients from Locally available foods, calculation of caloric needs of different groups (e.g. child, mother, sedentary lifestyle, etc.). Chart of glycemic index of foods.
17. Tobacco cessation, counselling, identifying various tobacco containing products through charts/pictures

Assignment

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. An overview of Women's Health Issues
2. Study the labels of various packed foods to understand their nutritional contents
3. Breastfeeding counselling, guidance – using Information, Education and Communication (IEC)
4. Information about the organations working on de-addiction services in the region (city / district, etc.)
5. Role of a pharmacist in disaster management – A case study
6. Overview on the National Tuberculosis Elimination Programme (NTEP)
7. Drug disposal systems in the country, at industry level and citizen level
8. Various Prebiotics or Probiotics (dietary and market products)
9. Emergency preparedness: Study of local Government structure with respect to Fire, Police departments, health department
10. Prepare poster/presentation for general public on any one of the Health Days. e.g. Day, AIDS Day, Hand washing Day, ORS day, World Diabetes Day, World Heart Day, etc.
11. List of home medicines, their storage, safe handling, and disposal of unused medicines
12. Responsible Use of Medicines: From Purchase to Disposal
13. Collection of newspaper clips (minimum 5) relevant to any one topic and its submission in an organized form with collective summary based on the news items
14. Read a minimum of one article relevant to any theory topic, from Pharma /Science/ or other Periodicals and prepare summary of it for submission
15. Potential roles of pharmacists in rural India

Field Visits

The students shall be taken in groups to visit any THREE of the following facilities to witness and understand the activities of such centres/facilities from the perspectives of the topics discussed in theory and/or practical courses. Individual reports from each student on their learning experience from the field visits shall be submitted.

1. Garbage Treatment Plant
2. Sewage Treatment Plant
3. Bio-medical Waste Treatment Plant
4. Effluent Treatment Plant
5. Water purification plant
6. Orphanage / Elderly-Care-Home / School and or Hostel/Home for persons with disabilities
7. Primary health care centre

ER-2020
D. Pharm Syllabus – Part II

S. No.	Course Code	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week
1.	ER20-21T	Pharmacology–Theory	75	25	3	1
2.	ER20-21P	Pharmacology–Practical	50	-	2	-
3.	ER20-22T	Community Pharmacy & Management–Theory	75	25	3	1
4.	ER20-22P	Community Pharmacy & Management–Practical	75	-	3	-
5.	ER20-23T	Biochemistry & Clinical Pathology – Theory	75	25	3	1
6.	ER20-23P	Biochemistry & Clinical Pathology – Practical	50	-	2	-
7.	ER20-24T	Pharmacotherapeutics Theory	75	25	3	1
8.	ER20-24P	Pharmacotherapeutics – Practical	25	-	1	-
9.	ER20-25T	Hospital & Clinical Pharmacy – Theory	75	25	3	1
10.	ER20-25P	Hospital & Clinical Pharmacy – Practical	25	-	1	-
11.	ER20-26T	Pharmacy Law & Ethics	75	25	3	1

PHARMACOLOGY – THEORY

Course Code: ER20-21T **75 Hours (3 Hours/week)**

Scope: This course provides basic knowledge about different classes of drugs available for the pharmacotherapy of common diseases. The indications for use, dosage regimen, routes of administration, pharmacokinetics, pharmacodynamics, and contraindications of the drugs discussed in this course are vital for successful professional practice.

Course Objectives: This course will discuss the following:

1. General concepts of pharmacology including pharmacokinetics, pharmacodynamics, routes of administration, etc.
2. Pharmacological classification and indications of drugs
3. Dosage regimen, mechanisms of action, contraindications of drugs
4. Common adverse effects of drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the basic concepts of pharmacokinetics and pharmacodynamics.
2. Enlist the various classes and drugs of choices for any given disease condition.
3. Advice the dosage regimen, route of administration and contraindications for a given drug.
4. Describe the common adverse drug reactions.

Chapter	Topic	Hours
1	**General Pharmacology** • Introduction and scope of Pharmacology • Various routes of drug administration - advantages and disadvantages • Drug absorption - definition, types, factors affecting drug absorption • Bioavailability and the factors affecting bioavailability • Drug distribution - definition, factors affecting drug distribution • Biotransformation of drugs - Definition, types of biotransformation reactions, factors influencing drug metabolisms • Excretion of drugs - Definition, routes of drug excretion • General mechanisms of drug action and factors modifying drug action.	**10**
2	**Drugs Acting on the Peripheral Nervous System** • Steps involved in neurohumoral transmission • Definition, classification, pharmacological actions, dose, indications, and contraindications of a) Cholinergic drugs b) Anti-Cholinergic drugs c) Adrenergic drugs d) Anti-adrenergic drugs e) Neuromuscular blocking agents f) Drugs used in Myasthenia gravis g) Local anaesthetic agents h) Non-Steroidal Anti-Inflammatory drugs (NSAIDs)	**11**

3	**Drugs Acting on the Eye** Definition, classification, pharmacological actions, dose, indications and contraindications of • Miotics • Mydriatics • Drugs used in Glaucoma	**2**
4	**Drugs Acting on the Central Nervous System** Definition, classification, pharmacological actions, dose, indications, and contraindications of • General anaesthetics • Hypnotics and sedatives • Anti-Convulsant drugs • Anti-anxiety drugs • Anti-depressant drugs • Anti-psychotics • Nootropic agents • Centrally acting muscle relaxants • Opioid analgesics	**8**
5	**Drugs Acting on the Cardiovascular System** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Anti-hypertensive drugs • Anti-anginal drugs • Anti-arrhythmic drugs • Drugs used in atherosclerosis and • Congestive heart failure • Drug therapy for shock	**6**
6	**Drugs Acting on Blood and Blood Forming Organs** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Hematinic agents • Anti-coagulants • Anti-platelet agents • Thrombolytic drugs	**4**
7	Definition, classification, pharmacological actions, dose, indications, and contraindications of • Bronchodilators • Expectorants • Anti-tussive agents • Mucolytic agents	**2**
8	**Drugs Acting on the Gastro Intestinal Tract** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Anti-ulcer drugs • Anti-emetics • Laxatives and purgatives • Anti-diarrheal drugs	**5**

9	**Drugs Acting on the Kidney** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Diuretics • Anti-Diuretics	**2**
10	**Hormones and Hormone Antagonists** Physiological and pathological role and clinical uses of • Thyroid hormones • Anti-thyroid drugs • Parathormone • Calcitonin • Vitamin D • Insulin • Oral hypoglycemic agents • Estrogen • Progesterone • Oxytocin • Corticosteroids	**8**
11	**Autocoids** • Physiological role of Histamine, 5 HT and Prostaglandins Classification, clinical uses, and adverse effects of antihistamines and 5 HT antagonists	**3**
12	**Chemotherapeutic Agents:** Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication and contraindications of drugs belonging to following classes: • Penicillins • Cephalosporins • Aminoglycosides • Fluoroquinolones • Macrolides • Tetracyclines • Sulphonamides • Anti-tubercular drugs • Anti-fungal drugs • Anti-viral drugs • Anti-amoebic agents • Anthelmintics • Anti-malarial agents • Anti-neoplastic agents	**12**
13	**Biologicals** Definition, types, and indications of biological agents with examples	**2**

HARMACOLOGY – PRACTICAL

Course Code: ER20-21P **50 Hours (2 Hours/week)**

Scope: This course provides the basic understanding about the uses, mechanisms of actions, dose dependent responses of drugs in simulated virtual animal models and experimental conditions.

Course Objectives: This course will demonstrate / provide hands-on experience in the virtual platform using appropriate software on the following

1. Study of pharmacological effects of drugs like local anaesthetics, mydriatic and mitotic on rabbit eye
2. Screening the effects of various drugs acting in the central nervous system
3. Study of drug effects on isolated organs / tissues
4. Study of pyrogen testing on rabbit

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Study and report the local anaesthetic, mydriatic and mitotic effects of the given drug on the rabbit eye
2. Choose appropriate animal experiment model to study the effects of the given drugs acting on the central nervous system and submit the report
3. Perform the effects of given tissues (simulated) on isolated organs / tissues and interpret the results
4. Interpret the dose dependent responses of drugs in various animal experiment models

Practical

Introduction to the following topics pertaining to the experimental pharmacology have to be discussed and documented in the practical manuals.

1. Introduction to experimental pharmacology
2. Study of laboratory animals
   (a) Mice; (b) Rats; (c) Guinea pigs; (d) Rabbits
3. Commonly used instruments in experimental pharmacology
4. Different routes of administration of drugs in animals
5. Types of pre-clinical experiments: In-Vivo, In-Vitro, Ex-Vivo, etc.
6. Techniques of blood collection from animals

Experiments

Note: Animals shall not be used for doing / demonstrating any of the experiments given. The given experiments shall be carried- out / demonstrated as the case may be, ONLY with the use of software program(s) such as ‘Ex Pharm’ or any other suitable software

1. Study of local anaesthetics on rabbit eye
2. Study of Mydriatic effect on rabbit eye
3. Study of Miotic effect on rabbit eye
4. Effect of analgesics using Analgesiometer
5. Study of analgesic activity by writhing test
6. Screening of anti-convulsant using Electro Convulsiometer

7. Screening of Muscle relaxants using Rota-Rod apparatus
8. Screening of CNS stimulants and depressants using Actophotometer
9. Study of anxiolytic activity using elevated plus maze method
10. Study of effect of drugs (any 2) on isolated heart
11. Effect of drugs on ciliary motility on frog's buccal cavity
12. Pyrogen testing by rabbit method

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Introduction to Allergy Testing
2. Introduction to Toxicity Studies
3. Drug Facts Labels of US FDA
4. Pre-clinical studies in new drug development
5. Medicines and meals: Before or After food
6. Pre-clinical studies in new drug development
7. Drugs available as paediatric formulations
8. Drug information apps

COMMUNITY PHARMACY AND MANAGEMENT – THEORY

Course Code: ER20-22T **75 Hours (3 Hours/week)**

Scope: The course is designed to impart basic knowledge and skills to provide various pharmaceutical care services to patients and general practitioners in the community setup.

Course Objectives: This course will discuss the following:

1. Establishing and running a community pharmacy and its legal requirements
2. Professional aspects of handling and filling prescriptions
3. Patient counselling on diseases, prescription and or non-prescription medicines
4. Scope for performing basic health screening in community pharmacy settings

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the establishment, legal requirements, and effective administration of a community pharmacy
2. Professionally handle prescriptions and dispense medications
3. Counsel patients about the disease, prescription and or non-prescription medicines
4. Perform basic health screening on patients and interpret the reports in the community pharmacy settings
5.

Chapter	Topic	Hours
1	**Community Pharmacy Practice** – Definition, history and development of community pharmacy - International and Indian scenarios	2
2	Professional responsibilities of community pharmacists Introduction to the concept of Good Pharmacy Practice and SOPs.	3
3	**Prescription and prescription handling** • Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage • Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them	7
4	**Communication skills** • Definition, types of communication skills • Interactions with professionals and patients • Verbal communication skills (one-to-one, over the telephone) • Written communication skills • Body language • Patient interview techniques	6
5	**Patient counselling** • Definition and benefits of patient counselling • **Stages of patient counselling** - Introduction, counselling content, counselling process, and closing the counselling session • **Barriers to effective counseling** - Types and strategies to overcome the barriers • **Patient counselling points for chronic diseases/disorders** -	10

	Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS • **Patient Package Inserts** - Definition, importance and benefits, Scenarios of PPI use in India and other countries • **Patient Information leaflets** - Definition and uses	
6	**Medication Adherence** Definition, factors influencing non- adherence, strategies to overcome non-adherence	**2**
7	**Health Screening Services in Community Pharmacy** Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases	**5**
9	**Over The Counter (OTC) Medications** • Definition, need and role of Pharmacists in OTC medication dispensing • OTC medications in India, counseling for OTC products • Self-medication and role of pharmacists in promoting the safe practices during self-medication • Responding to symptoms, minor ailments, and advice for self-care in conditions such as - Pain management, Cough, Cold, Diarrhea, Constipation, Vomiting, Fever, Sore throat, Skin disorders, Oral health (mouth ulcers, dental pain, gum swelling)	**15**
10	**Community Pharmacy Management** • Legal requirements to set up a community pharmacy • Site selection requirements • Pharmacy designs and interiors • Vendor selection and ordering • Procurement, inventory control methods, and inventory management • Financial planning and management • Accountancy in community pharmacy – Day book, Cash book • Introduction to pharmacy operation softwares – usefulness and availability • Customer Relation Management (CRM) • Audits in Pharmacies • SOP of Pharmacy Management • Introduction to Digital Health, Health and Online pharmacies	**25**

COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

Course Code: ER20-22P **75 Hours (3 Hours/week)**

Scope: The course is designed to train the students and improve professional skills to provide various pharmaceutical care services in community pharmacy.

Course Objectives: This course will train the students in the following

1. Professional handling and filling prescriptions
2. Patient counselling on diseases and minor ailments
3. Patient counselling on prescription and / or non-prescription medicines
4. Preparation of counselling materials such as patient information leaflets
5. Performing basic health screening tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Handle and fill prescriptions in a professional manner
2. Counsel patients on various diseases and minor ailments
3. Counsel patients on prescription and or non-prescription medicines
4. Design and prepare patient information leaflets
5. Perform basic health screening tests

Practical

Note: The following practicals shall be carried out in the model community pharmacy with appropriate simulated scenarios and materials. Students shall be trained through role plays wherever necessary. The activities of the students shall be assessed / evaluated using a structured objective assessment form.

1. Handling of prescriptions with professional standards, reviewing prescriptions, checking for legal compliance and completeness (minimum 5)
2. Identification of drug-drug interactions in the prescription and follow-up actions (minimum 2)
3. Preparation of dispensing labels and auxiliary labels for the prescribed medications (minimum 5)
4. Providing the following health screening services for monitoring patients / detecting new patients (one experiment for each activity) Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement
5. Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease) Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
6. Providing counselling to simulated patients for the following minor ailments (any three) Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
7. Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
8. Use of Community Pharmacy Software and digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)
2. List out the various abbreviations, short forms used in prescriptions and their interpretation
3. Patient Information Leaflet for a given chronic disease / disorder
4. Patient Information Leaflet for prescription / non-prescription medicines
5. Preparation of window / shelf display materials for the model community pharmacy
6. Overview of Software available for retail pharmacy management including billing, inventory, etc.
7. Dosage / Medication Reminder Aids
8. Overview on the operations and marketing strategies of various online pharmacies
9. Overview on the common fixed dose combinations
10. Overview on the medications requiring special storage conditions
11. Role of Community Pharmacists in preventing Antimicrobial Resistance
12. Jan Aushadhi and other Generic Medicine initiatives in India
13. Global Overview of Online Pharmacies
14. Community Pharmacy Practice Standards: Global Vs. Indian Scenario
15. Overview of pharmacy associations in India

Field Visit

The students shall be taken in groups to visit community pharmacies and medicine distributors to understand and witness the professional activities of the community pharmacists, and supply chain logistics. Individual reports from each student on their learning experience from the field visit shall be submitted.

BIOCHEMISTRY & CLINICAL PATHOLOGY – THEORY

Course Code: ER20-23T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on the study of structure and functions of bio molecules and the chemical processes associated with living cells in normal and abnormal states. The course also emphasizes on the clinical pathology of blood and urine.

Course Objectives: This course will discuss the following at the fundamental level

1. Structure and functions of bio molecules
2. Catalytic activity, diagnostic and therapeutic importance of enzymes
3. Metabolic pathways of bio molecules in health and illness (metabolic disorders)
4. Biochemical principles of organ function tests and their clinical significance
5. Qualitative and quantitative determination of bio molecules / metabolites in the biological sample
6. Clinical pathology of blood and urine

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the functions of bio molecules
2. Discuss the various functions of enzymes in the human system
3. Explain the metabolic pathways of bio molecules in both physiological and pathological conditions
4. Describe the principles of organ function tests and their clinical significances
5. Determine the bio molecules / metabolites in the given biological samples, both qualitatively and quantitatively
6. Describe the clinical pathology of blood and urine

Chapter	Topic	Hours
1	**Introduction to biochemistry**: Scope of biochemistry in pharmacy; Cell and its biochemical organization.	2
2	**Carbohydrates** • Definition, classification with examples, chemical properties • Monosaccharides - Structure of glucose, fructose, and galactose • Disaccharides - structure of maltose, lactose, and sucrose • Polysaccharides - chemical nature of starch and glycogen • Qualitative tests and biological role of carbohydrates	5
3	**Proteins** • Definition, classification of proteins based on composition and solubility with examples • Definition, classification of amino acids based on chemical nature and nutritional requirements with examples • Structure of proteins (four levels of organization of protein structure) • Qualitative tests and biological role of proteins and amino acids • Diseases related to malnutrition of proteins.	5

4	**Lipids** • Definition, classification with examples • Structure and properties of triglycerides (oils and fats) • Fatty acid classification – Based on chemical and nutritional requirements with examples • Structure and functions of cholesterol in the body • Lipoproteins - types, composition and functions in the body • Qualitative tests and functions of lipids	**5**
5	**Nucleic acids** • Definition, purine and pyrimidine bases • Components of nucleosides and nucleotides with examples • Structure of DNA (Watson and Crick model), RNA and their functions	**4**
6	**Enzymes** • Definition, properties and IUB and MB classification • Factors affecting enzyme activity • Mechanism of action of enzymes, Enzyme inhibitors • Therapeutic and pharmaceutical importance of enzymes	**5**
7	**Vitamins** • Definition and classification with examples • Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins	**6**
8	**Metabolism** (Study of cycle/pathways without chemical structures) Metabolism of Carbohydrates: Glycolysis, TCA cycleand glycogen metabolism, regulation of blood glucose level. Diseases related to abnormal metabolism of Carbohydrates	**20**
	• Metabolism of lipids: Lipolysis, β-oxidation of Fatty acid (Palmitic acid) ketogenesis and ketolysis. Diseases related to abnormal metabolism of lipids such as Ketoacidosis, Fatty liver, Hypercholesterolemia • Metabolism of Amino acids (Proteins): General reactions of amino acids and its significance– Transamination, deamination, Urea cycle and decarboxylation. Diseases related to abnormal metabolism of amino acids, Disorders of ammonia metabolism, phenylketonuria, alkaptonuria and Jaundice. • Biological oxidation: Electron transport chain and Oxidative phosphorylation	
9	**Minerals**: Types, Functions, Deficiency diseases, recommended dietary requirements	**05**
10	**Water and Electrolytes** • Distribution, functions of water in the body • Water turnover and balance • Electrolyte composition of the body fluids, Dietary intake of electrolyte and Electrolyte balance • Dehydration, causes of dehydration and oral rehydration therapy	**05**
11	Introduction to Biotechnology	**01**
12	**Organ function tests**	**06**

	• Functions of kidney and routinely performed tests to assess the functions of kidney and their clinical significances • Functions of liver and routinely performed tests to assess the functions of liver and their clinical significances • Lipid profile tests and its clinical significances	
13	**Introduction to Pathology of Blood and Urine** • Lymphocytes and Platelets, their role in health and disease • Erythrocytes - Abnormal cells and their significance • Normal and Abnormal constituents of Urine and their significance	**06**

BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P **50 Hours (2 Hours/week)**

Scope: This course is designed to train the students in the qualitative testing of various bio molecules and testing of biological samples for determination of normal and abnormal constituents

Course Objectives: This course will train and provide hands-on experiences on the following

1. Qualitative determination of biomolecules / metabolites in simulated biological samples
2. Determination of normal and abnormal constituents of simulated blood and urine samples

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Qualitatively determine the bio molecules / metabolites in the given biological samples.
2. Determine the normal and abnormal constituents in blood and urine samples and interpret the results of such testing

Practical

1. Qualitative analysis of carbohydrates (4 experiments)
2. Qualitative analysis of Proteins and amino acids (4 experiments)
3. Qualitative analysis of lipids (2 experiments)
4. Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
5. Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)
6. Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
7. Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

The students shall be asked to submit written assignments on Various Pathology Lab Reports (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

PHARMACOTHERAPEUTICS - THEORY

Course Code: ER20-24T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on etiopathogenesis of common diseases and their management along with quality use of medicines.

Course Objectives: This course will discuss about

1. Etiopathogenesis of selected common diseases and evidence-based medicine therapy.
2. Importance of individualized therapeutic plans based on diagnosis
3. Basic methods for assessing the clinical outcomes of drug therapy

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Help assessing the subjective and objective parameters of patients in common disease conditions
2. Assist other healthcare providers to analyse drug related problems and provide therapeutic interventions
3. Participate in planning the rational medicine therapy for common diseases
4. Design and deliver discharge counselling for patients
5.

Chapter	Topic	Hours
1	Pharmacotherapeutics – Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs)	8
2	**Definition, etiopathogenesis, clinical manifestations, non-pharmacological and pharmacological management of the diseases associated with**	
	(a) Cardiovascular System • Hypertension • Angina and Myocardial infarction • Hyperlipidaemia • Congestive Heart Failure	**8**
	(b) Respiratory System • Asthma • COPD	**4**
	(c) Endocrine System • Diabetes • Thyroid disorders - Hypo and Hyperthyroidism	**5**
	(d) Central Nervous System • Epilepsy	**8**
	• Parkinson's disease • Alzheimer's disease • Stroke • Migraine	
	(e) Gastro Intestinal Disorders • Gastro oesophageal reflux disease	**8**

	• Peptic Ulcer Disease • Alcoholic liver disease • Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis)	
	(f) Haematological disorders • Iron deficiency anaemia • Megaloblastic anaemia	**4**
	(g) Infectious diseases • Tuberculosis • Pneumonia • Urinary tract infections • Hepatitis • Gonorrhoea and Syphilis • Malaria • HIV and Opportunistic infections • Viral Infections (SARS, CoV2)	**12**
	(h) Musculoskeletal disorders • Rheumatoid arthritis • Osteoarthritis	**3**
	(i) Dermatology • Psoriasis • Scabies • Eczema	**3**
	(j) Psychiatric Disorders • Depression • Anxiety • Psychosis	**4**
	(k) Ophthalmology • Conjunctivitis (bacterial and viral) • Glaucoma	**2**
	(l) Anti-microbial Resistance	**2**
	(m) Women's Health • Polycystic Ovary Syndrome • Dysmenorrhea • Premenstrual Syndrome	**4**

PHARMACOTHERAPEUTICS – PRACTICAL

Course Code: ER20-24P **25 Hours (1 Hour/week)**

Scope: This course is designed to train the students in the basic skills required to support the pharmaceutical care services for selected common disease conditions.

Course Objectives: This course will train the students on

1. How to prepare a SOAP (Subjective, Objective, Assessment and Plan) note for clinical cases of selected common diseases
2. Patient counselling techniques/methods for common disease conditions

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Write SOAP (Subjective, Objective, Assessment and Plan) notes for the given clinical cases of selected common diseases
2. Counsel the patients about the disease conditions, uses of drugs, methods of handling and administration of drugs, life-style modifications, and monitoring parameters.

Practical

1. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions.
    1. Hypertension
    2. Angina Pectoris
    3. Myocardial Infarction
    4. Hyperlipidaemia
    5. Rheumatoid arthritis
    6. Asthma
    7. COPD
    8. Diabetes
    9. Epilepsy
    10. Stroke
    11. Depression
    12. Tuberculosis
    13. Anaemia (any one type as covered in theory)
    14. Viral infection (any one type as covered in theory)
    15. Dermatological conditions (any one condition as covered in theory)

2. Patient counselling exercises using role plays based on the real / hypothetical clinical case scenarios. The students are expected to provide counselling on disease condition, medications, life-style modifications, monitoring parameters, etc. and the same shall be documented. (Minimum 5 cases)

3. Simulated cases to enable dose calculation of selected drugs in paediatrics, and geriatrics under various pathological conditions. (Minimum 4 cases)

HOSPITAL AND CLINICAL PHARMACY – THEORY

Course Code: ER20-25T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart fundamental knowledge and professional skills required for facilitating various hospital and clinical pharmacy services.

Course Objectives: This course will discuss and train the students in the following

1. Hospital and Hospital Pharmacy organization and set-ups
2. Basics of hospital pharmacy services including the procurement, supply chain, storage of medicines and medical supplies
3. Basics of clinical pharmacy including introduction to comprehensive pharmaceutical care services.
4. Basic interpretations of common laboratory results used in clinical diagnosis towards optimizing the drug therapy

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Explain about the basic concepts of hospital pharmacy administration
2. Manage the supply chain and distribution of medicines within the hospital settings
3. Assist the other healthcare providers in monitoring drug therapy and address drug related problems
4. Interpret common lab investigation reports for optimizing drug therapy

S. No.	Topic	Hours
1	**Hospital Pharmacy** • Definition, scope, national and international scenario • Organisational structure • Professional responsibilities, Qualification and experience requirements, job specifications, work load requirements and inter professional relationships • Good Pharmacy Practice (GPP) in hospital • Hospital Pharmacy Standards (FIP Basel Statements, AHSP) • Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists	6
2	**Different Committees in the Hospital** • Pharmacy and Therapeutics Committee - Objectives, Composition, and functions • Hospital Formulary - Definition, procedure for development and use of hospital formulary	4
	• Infection Control Committee – Role of Pharmacist in preventing Antimicrobial Resistance	
4	**Supply Chain and Inventory Control** • Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics • Procedures of Drug Purchases – Drug selection, short term, long term, and tender/e-tender process, quotations, etc. • Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc.	14

	• Inventory Management of Central Drug Store – Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold rooms) • FEFO, FIFO methods • Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs • Documentation - purchase and inventory	
5	**Drug distribution** • Drug distribution (in- patients and out - patients) – Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method. • Distribution of drugs to ICCU/ICU/NICU/Emergency wards. • Automated drug dispensing systems and devices • Distribution of Narcotic and Psychotropic substances and their storage	**7**
6	Compounding in Hospitals. Bulk compounding, IV admixture services and incompatibilities, Total parenteral nutrition	**4**
7	**Radio Pharmaceuticals** - Storage, dispensing and disposal of radiopharmaceuticals	**2**
8	Application of computers in Hospital Pharmacy Practice, Electronic health records, Softwares used in hospital pharmacy	**2**
9	**Clinical Pharmacy:** Definition, scope, and development - in India and other countries Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc.	**12**
	Daily activities of clinical pharmacists: Definition, goal, and procedure of • Ward round participation • Treatment Chart Review • Adverse drug reaction monitoring • Drug information and poisons information • Medication history • Patient counselling • Interprofessional collaboration **Pharmaceutical care**: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care **Medication Therapy Management, Home Medication Review**	
10	**Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results** • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Pulmonary Function Tests	**10**
11	**Poisoning**: Types of poisoning: Clinical manifestations and Antidotes **Drugs and Poison Information Centre and their services** – Definition, Requirements, Information resources with examples, and their advantages and disadvantages	**6**

12	**Pharmacovigilance** • Definition, aim and scope • Overview of Pharmacovigilance	**2**
13	**Medication errors**: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP **Drug Interactions:** Definition, types, clinical significance of drug interactions	**6**

HOSPITAL AND CLINICAL PHARMACY – PRACTICAL

Course Code: ER20-25P **25 Hours (1 Hour / Week)**

Scope: This course is designed to train the students to assist other healthcare providers in the basic services of hospital and clinical pharmacy.

Course Objectives: This course will train the students with hands-on experiences, simulated clinical case studies in the following:

1. Methods to systematically approach and respond to drug information queries
2. How to interpret common laboratory reports to understand the need for optimizing dosage regimens
3. How to report suspected adverse drug reactions to the concerned authorities
4. Uses and methods of handling various medical/surgical aids and devices
5. How to interpret drug-drug interactions in the treatment of common diseases.

Course Outcomes: Upon completion of the course, the students will be able to

1. Professionally handle and answer the drug information queries
2. Interpret the common laboratory reports
3. Report suspected adverse drug reactions using standard procedures
4. Understand the uses and methods of handling various medical/surgical aids and devices
5. Interpret and report the drug-drug interactions in common diseases for optimizing the drug therapy

Note: Few of the experiments of Hospital and Clinical Pharmacy practical course listed here require adequate numbers of desktop computers with internet connectivity, adequate drug information resources including reference books, different types of surgical dressings and other medical devices and accessories. Various charts, models, exhibits pertaining to the experiments shall also be displayed in the laboratory.

Practical

1. Systematic approach to drug information queries using primary / secondary / tertiary resources of information (2 cases)
2. Interpretation of laboratory reports to optimize the drug therapy in a given clinical case (2 cases)
3. Filling up IPC's ADR Reporting Form and perform causality assessments using various scales (2 cases)
4. Demonstration / simulated / hands-on experience on the identification, types, use / application /administration of
   - Orthopaedic and Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc.
   - Different types of bandages such as sterile gauze, cotton, crepe bandages, etc.
   - Needles, syringes, catheters, IV set, urine bag, RYLE's tube, urine pots, colostomy bags, oxygen masks, etc.
5. Case studies on drug-drug interactions (any 2 cases)
6. Wound dressing (simulated cases and role play –minimum 2 cases)
7. Vaccination and injection techniques (IV, IM, SC) using mannequins (5 activities)

8. Use of Hospital Pharmacy Software and various digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Typical profile of a drug to be included in the hospital formulary
2. Brief layout and various services of the Central Sterile Supplies Department (CSSD)
3. Various types of sterilizers and sterilization techniques used in hospitals
4. Fumigation and pesticide control in hospitals
5. Role of Pharmacists in Transition of Care: Discharge cards, post hospitalization care, medicine reconciliation activities in developed countries
6. Total parenteral nutrition and IV admixtures and their compatibility issues
7. Concept of electronic health records
8. Invasive and Non-invasive diagnostic tests - HRCT, MRI, Sonography, 2D ECHO, X-rays, Mammography, ECG, EMG, EEG
9. Home Diagnostic Kits - Pregnancy Test, COVID testing etc
10. Measures to be taken in hospitals to minimize Antimicrobial Resistance
11. Role and responsibilities of a pharmacist in public hospital in rural parts of the country
12. Safe waste disposal of hospital waste

Field Visit

The students shall be taken in groups to visit a Government / private healthcare facility to understand and witness the various hospital and clinical pharmacy services provided. Individual reports from each student on their learning experience from the field visit shall be submitted.

PHARMACY LAW AND ETHICS – THEORY

Course Code: ER20-26T **75 Hours (3 Hours/week)**

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

Course Objectives: This course will discuss the following
1. General perspectives, history, evolution of pharmacy law in India
2. Act and Rules regulating the profession and practice of pharmacy in India
3. Important code of ethical guidelines pertaining to various practice standards
4. Brief introduction to the patent laws and their applications in pharmacy

Course Outcomes: Upon successful completion of this course, the students will be able to
1. Describe the history and evolution of pharmacy law in India
2. Interpret the act and rules regulating the profession and practice of pharmacy in India
3. Discuss the various codes of ethics related to practice standards in pharmacy
4. Interpret the fundamentals of patent laws from the perspectives of pharmacy

Chapter	Topics	Hours
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	**2**
2	**Pharmacy Act-1948 and Rules:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. **Pharmacy Practice Regulations 2015**	**5**
3	**Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments** Objectives, Definitions, Legal definitions of schedules to the Act and Rules **Import of drugs** – Classes of drugs and cosmetics prohibited from import, Import under license or permit.	**23**
	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. Study of schedule C and C1, G, H, H1, K, P, M, N, and X. ***Sale of Drugs*** – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India ***Administration of the Act and Rules*** – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.	
4	**Narcotic Drugs and Psychotropic Substances Act 1985 and Rules** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	**2**
5	**Drugsand Magic Remedies (Objectionable Advertisements) Act 1954** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	**2**
6	**Prevention of Cruelty to Animals Act-1960**: Objectives, Definitions,	**2**

	CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	
7	**Poisons Act-1919**: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	**2**
8	**FSSAI (Food Safety and Standards Authority of India) Act and Rules**: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	**2**
9	**National Pharmaceutical Pricing Authority**: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	**5**
10	**Code of Pharmaceutical Ethics**: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	**5**
11	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	**2**
12	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	**1**
13	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business**,** inspections, import, export of drugs and medical devices	**3**
14	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	**7**
15	Blood bank – basic requirements and functions	**2**
16	Clinical Establishment Act and Rules – Aspects related to Pharmacy	**2**
17	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	**2**
18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	**2**
19	Introduction to the Consumer Protection Act	**1**
20	Introduction to the Disaster Management Act	**1**
21	Medical Devices – Categorization, basic aspects related to manufacture and sale	**2**

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements
2. Layout and contents of official websites of various agencies regulating the profession of

pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.

3. Licenses required, application processes (online/offline), drug regulatory office website of the respective state
4. Case studies – actions taken on violation of any act / rule related to pharmacy
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Overview of Pharma marketing practices
9. Generic Medicines

9. **Appendices**

S. No	Appendix Document
1.	A typical format for the assessment of an Assignment
2.	A typical format for the assessment of a Field Visit Report
3.	Recommended Books

Appendix – 1

A typical format for the assessment of an Assignment

Name of the College:

Name of the Student:	
Academic Year of the Student:	
Name of the Subject:	
Title of the Assignment:	
Date on which the Assignment was given:	
Date on which the Assignment was submitted:	
Name & Designation of the Evaluator:	
Signature of the Evaluator with Date:	

Directions: For **evaluation,** enter rating of the student utilizing the following scale: 5 – Excellent; 4 - Very Good; 3 – Good; 2 – Satisfactory; 1 – Poor

Assessment Criteria	Score	Comments if any
a. Relevance with the content		
b. Use of resource material		
c. Organization & mechanical accuracy		
d. Cohesion & coherence		
e. Language proficiency & Timely submission		
Total Score		

Signature of the Student with Date:

Note: Subject teacher should try to cover all assignments mentioned in the list for each practical subject by assigning the topics to the students. Students should be encouraged to submit an assignment (in a format decided by the Institute) and encouraged to present assignments (at least any one assignment per subject) in the class**.**

Appendix – 2

A typical format for the assessment of a Field Visit Report

Name of the College:

Name of the Student:	
Academic Year of the Student:	
Name of the Subject:	
Name & full address of the organization visited:	
Date and Duration of Visit:	
Name & Designation of the Evaluator:	
Signature of the Evaluator with Date:	

Objectives set for the field visit: (give 2 – 4 objectives one by one)
Prior preparation of the student for the field visit: (minimum 100 words)
Describe the general experiences during the field visit: (minimum 100 words)
Learning points: Describe what theoretical concept that is correlated during the field visit: (minimum 300 words)

Recommended Books

Pharmaceutics

1. History of Pharmacy in India by Dr. Harikishan Singh
2. Indian Pharmacopoeia, Govt. of India Publication
3. A Text book of Pharmaceuticals Formulation by B.M. Mithal, Vallabh Prakashan.
4. Bentleys' Text book of Pharmaceutics, Editor E.A. Rawlins, Elsevier Int.,
5. The Theory and Practice of Industrial Pharmacy. Leon Lachman, Herbert Lieberman and Joseph Kanig, Editors, Lea and Febiger, Philadelphia. Varghese Publishing House
6. Responsible Use of Medicines: A Layman's Handbook, www.ipapharma.org / publications

Pharmaceutical Chemistry

1. Medicinal & Pharmaceutical chemistry by Harikishan Singh and VK Kapoor
2. Wilson and Griswold's Text book of Organic Medicinal and pharmaceutical Chemistry
3. Practical Organic Chemistry by Mann and Saunders.
4. Practical Pharmaceutical Chemistry, Volume- I & II by Beckett and J. B. Stenlake
5. Indian Pharmacopoeia
6. Vogel's text book of Practical Organic Chemistry

Pharmacognosy

1. Text book of Pharmacognosy by C. K. Kokate, S. B. Gokhale, A.P. Purohit, Nirali Prakashan
2. Text book of Pharmacognosy by C.S. Shah and J. S. Qadry, CBS Publishers & Distributors Pvt. Ltd.
3. Text Book of Pharmacognosy by T. E. Wallis. CBS Publishers & Distributors Pvt. Ltd.
4. Study of crude drugs by M. A. Iyengar, Manipal Press Ltd, Manipal
5. Powder crude drugs by M. A. Iyengar, Manipal Press Ltd, Manipal
6. Anatomy of crude drugs by M. A. Iyengar, Manipal Press Ltd, Manipal
7. Augmented Text Book of Homeopathic Pharmacy by Dr. D D Banerjee, B Jain Publishers (P) Ltd

Human Anatomy and Physiology

1. Human Physiology by C. C. Chatterjee
2. Human Anatomy and Physiology by S. Chaudhary and A. Chaudhary
3. Derasari and Gandhi's elements of Human Anatomy, Physiology and Health Education
4. S.R. Kale and R.R. Kale, Textbook of Practical Anatomy and Physiology
5. Ross and Wilson Anatomy and Physiology in Health and illness
6. Human Anatomy and Physiology by Tortora Gerard J
7. Fundamentals of Medical Physiology by K. Sambulingam and P Sambulingam
8. Ranade V.G. Text Book of Practical Physiology
9. Goyal R.K., Natvar M.P. and Shah S.A., Practical Anatomy, Physiology and Biochemistry, Experimental Physiology

Social Pharmacy

1. Social Pharmacy – Innovation and development. Geoff Harding, Sarah Nettleton and Kevin Taylor. The Pharmaceutical Press.
2. Text Book of Community Pharmacy Practice. RPSGB Publication
3. Community Pharmacy Handbook- Jonathan Water field
4. S Khurana, P Suresh and R Kalsi. Health Education & Community Pharmacy. S Vikas & Co
5. Social Pharmacy: Tayler, Geoffrey. Pharmaceutical Press. London.
6. Textbook by Dandiya PC, Zafer ZYK, Zafer A. Health education & Community Pharmacy. Vallabh Prakashan.
7. Websites of Ministry of Health and Family Welfare, National Health Portal
8. Pharmacists at the Frontlines: A Novel Approach at Combating TB www.ipapharma.org Visit Publications
9. Where There Is No Doctor: A Village Health Care Handbook by David Werner, 2015 updated version
10. Various WHO publications www.who.int

Pharmacology

1. Pharma Satoskar, R.S. and Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics
2. B. Suresh, A Text Book of Pharmacology
3. Derasari and Gandhi's Elements of Pharmacology
4. S.K. Kulkarni, Practical Pharmacology and Clinical Pharmacy
5. H.K. Sharma. Principles of Pharmacology
6. Mary J. Mycek, Lippincott Williams and Wilkins. Lippincott's illustrated Reviews: Pharmacology
7. Tripathi, K.D. Essentials of Medical Pharmacology.
8. Various Drug Information Books like British National Formulary, MIMS, CIMS, Drug Today etc., WHO, NIH Websites

Community Pharmacy and Management

1. Health Education and Community Pharmacy by N.S. Parmar.
2. WHO consultative group report.
3. Drug store and Business management by Mohammed Ali and Jyoti.
4. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical Press
5. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams and Wilkins.
6. Good Pharmacy Practices Training Manual by IPA/CDSCO/WHO India
7. Training Module for Community Pharmacists in TB Care and Control/ by MoH/IPA
8. Hand Book of Pharma SoS, Drugs in Special population- Pregnancy and Lactation, Tobacco free future- Choice is yours: KSPC Publications.
9. Responsible Use of Medicines: A Layman's Handbook, www.ipapharma.org /publications
10. Community Pharmacy Practice around the Globe: Part One: www.ipapharma.org /publications

Biochemistry and Clinical Pathology

1. Essentials of Biochemistry by U. Satyanarayana, Books and Allied (P) Ltd.
2. A Textbook of Biochemistry by A.V.S.S. Rama Rao, UBS Publishers' Distributors Pvt. Ltd.
3. Practical Biochemistry by R.C. Gupta and S. Bhargava.
4. Laboratory manual of Biochemistry by Pattabiraman and Sitaram Acharya

Pharmacotherapeutics

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone Publication
2. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
3. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA Lippincott, Williams and Wilkins Publication.
4. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton and Lange Publication.
5. National Formulary of India, Indian Pharmacopoeia Commission, Ghaziabad.

Hospital and Clinical Pharmacy

1. A Textbook of Clinical Pharmacy Practice - Essential concepts and skills - Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata. Orient Longman Pvt. Ltd. Hyderabad.
2. Text Book of Hospital and Clinical Pharmacy by Dr. Pratibha Nand and Dr**.** Roop K Khar, Birla publications, New Delhi.
3. Gupta B.K and Gupta R.N., GPP in Hospital Pharmacy, Vallabh Prakashan.
4. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
5. Australian drug information- Procedure manual. The Society of Hospital Pharmacists of Australia.

Pharmacy Law and Ethics

1. Text book of Forensic Pharmacy by B.M. Mithal
2. Forensic Pharmacy by B. Suresh
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 publications.
9. CDSCO Website, NPPA Website
10. Books on Drugs and Cosmetic Act by Nilesh Gandhi and Sudhir Deshpande
11. Text Book of Forensic Pharmacy by Dr Guruprasad Mohanta

IIMT College of Medical Sciences (Pharmacy)

ACADEMIC HAND BOOK

(AS PER PHARMACY COUNCIL OF INDIA, NEW DELHI)
RULES & SYLLABUS FOR THE BACHELOR OF PHARMACY (B. PHARM) COURSE
[FRAMED UNDER REGULATION 6, 7 & 8 OF THE BACHELOR OF PHARMACY (B. PHARM) COURSE REGULATIONS 2014]

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

First year B. Pharm:

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

7.2. Minimum credit requirements

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

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

8. Academic work

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

9. Course of study

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

Table-I: Course of study for semester I

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

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

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

* Non University Examination (NUE)

Table-II: Course of study for semester II

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

*Non University Examination (NUE)

Table-III: Course of study for semester III

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

Table-IV: Course of study for semester IV

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

Table-V: Course of study for semester V

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

Table-VI: Course of study for semester VI

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

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial PharmacyII – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
Total		**28**	**5**	**24**

* Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

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

Table-IX: Semester wise credits distribution

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

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

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

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

10. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Program Committee shall be as follows:
   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.
3. Duties of the Program Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the

course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.

v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

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

11.1. End semester examinations

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

Tables-X: Schemes for Internal Assessments and End Semester Examinations Semester Wise

Semester I

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

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

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

* Non University Examination (NUE)

Semester II

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

* The subject experts at college level shall conduct examinations

Semester III

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

Semester IV

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

Semester V

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

Semester VI

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

Semester VII

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

* The subject experts at college level shall conduct examinations

Semester VIII

Course Code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbals – Theory							
BP807ET	Computer Aided Drug Design –Theory							
BP808ET	Cell and Molecular Biology –Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology –Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150
Total		**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

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) OR	=	$10 \times 1 = 10$
	Objective Type Questions (5 x 2)	=	OR
	(Answer all the questions)	=	$05 \times 2 = 10$
II.	Long Answers (Answer 1 out of 2)	=	$1 \times 10 = 10$
III.	II. Short Answers (Answer 2 out of 3)		$2 \times 05 = 10$
	Total	**=**	**30 marks**

For subjects having Non University Examination

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

Question paper pattern for practical sessional examinations	=	10
I. Synopsis	=	25
II. Experiments	=	05
III. Viva voce		
Total	**=**	**40 marks**

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

A studentshall have the opportunity to improvehis/her performance only oncein the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

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

Table-XIII: Tentative schedule of end semester examinations

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

Question paper pattern for end semester theory examinations

For 75 marks paper

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

For 50 marks paper

I.	Long Answers (Answer 2 out of 3)	=	2 ×10 = 20
II.	Short Answers (Answer 6 out of 8)	=	6 × 5 = 30
Total		**=**	**50 marks**

	=	1 x 10 =10

For 35 marks paper

I.	Long Answers (Answer 1 out of 2)		
II.	Short Answers (Answer 5 out of 7)	=	5 × 5 = 25
Total		**=**	**35 marks**

Question paper pattern for end semester practical examinations

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5
Total	**=**	**35 marks**

16. Academic Progression:

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

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

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

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

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

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

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

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

Any student who hasgiven 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 ABshould 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 obtainedin 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 pointsin these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

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

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 ABSgrade awarded in that semester. For example if a learner has F or ABS grade in course 4, theSGPA shall then be computed as:

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

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 statusin case of F grade(s), till the course(s) is/are passed. When the course(s)is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

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

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

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows: First Class with Distinction = CGPA of. 7.50 And above First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a projectunder the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in

group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

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

Evaluation of Dissertation Book:

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

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 leveland grade point shall be awarded.

24. Award of Ranks

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

25. Award of degree

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

26. Duration for completion of the program of study

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

27. Re-admission after break of study

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

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

CHAPTER - II: SYLLABUS

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

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

Course Content:

Unit I **10 hours**

- **Introduction to human body**
  Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

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

- **Tissue level of organization**
  Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II

- **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 10 hours
- **Joints**

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

Unit III **10 hours**

- **Body fluids and blood**

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

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

Unit IV **08 hours**

Peripheral nervous system:
Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.

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

Unit V **07 hours**

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

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

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

Recommended Books (Latest Editions)

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

Reference Books (Latest Editions)

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

BP102T. PHARMACEUTICAL ANALYSIS (Theory) **45 Hours**

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

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

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

Course Content:

UNIT-I **10 Hours**

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

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

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

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

UNIT-II **10 Hours**

- **Acid base titration**: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves

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

UNIT-III **10 Hours**

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

- **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

- **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

- Basic Principles, methods and application of diazotisation titration.

UNIT-IV **08 Hours**

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)
Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V **07 Hours**

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

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Limit Test of the following

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

II Preparation and standardization of

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

III Assay of the following compounds along with Standardization of Titrant

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

IV Determination of Normality by electro-analytical methods

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

Recommended Books: (Latest Editions)

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

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

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

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

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

Course Content:

UNIT – I **10 Hours**

- **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

- **Dosage forms:** Introduction to dosage forms, classification and definitions

- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.

- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II **10 Hours**

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III **08 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

- **Biphasic liquids:**

  Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

  Emulsions: Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V **07 Hours**

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

BP109P. PHARMACEUTICSI (Practical)

3 Hours / week

1. Syrups

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

2. Elixirs

a) Piperazine citrate elixir
b) Paracetamol pediatric elixir

Linctus

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

3. Solutions

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

2. Suspensions

a) Calamine lotion
b) Magnesium Hydroxide mixture
c) Aluminimum Hydroxide gel

3. Emulsions

a) Turpentine Liniment
b) Liquid paraffin emulsion

4. Powders and Granules

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

5. Suppositories

a) Glycero gelatin suppository
b) Coca butter suppository
c) Zinc Oxide suppository

8. Semisolids

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

9. Gargles and Mouthwashes

a) Iodine gargle
b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System,

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

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

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

Objectives: Upon completion of course student shall be able to

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

Course Content:

UNIT I **10 Hours**

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

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

UNIT II **10 Hours**

- **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

- **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.

- **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III **10 Hours**

- **Gastrointestinal agents**

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen

peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV **08 Hours**

- **Miscellaneous compounds**

Expectorants: Potassium iodide, Ammonium chloride*. **Emetics**: Copper sulphate*, Sodium potassium tartarate **Haematinics:** Ferrous sulphate*, Ferrous gluconate
Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite333
Astringents: Zinc Sulphate, Potash Alum

UNIT V **07 Hours**

- **Radiopharmaceuticals**: Radio activity, Measurement of radioactivity, Properties of α, β, 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

I **Limit tests for following ions**

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

II **Identification test**

Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

III **Test for purity**

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

IV **Preparation of inorganic pharmaceuticals**

Boric acid Potash alum ferrous sulphate

Recommended Books (Latest Editions)

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

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

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

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials
6.

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? Dos 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, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2nd Edition, New arrivals–PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

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

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

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

UNIT I **07 Hours**

Living world:

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

Morphology of Flowering plants

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

UNIT II **07 Hours**

Body fluids and circulation

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

Digestion and Absorption

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

Breathing and respiration

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

UNIT III **07 Hours**

Excretory products and their elimination

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

Neural control and coordination

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

Chemical coordination and regulation

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

Human reproduction

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

UNIT IV **05 Hours**

Plants and mineral nutrition:

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

Photosynthesis

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

UNIT V **04 Hours**

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

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators
-

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

- Definition, types of tissues, location and functions.

Text Books

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112 RBP. REMEDIAL BIOLOGY (Practical)

30 Hours

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

Reference Books

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

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

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

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

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

Course Content:

UNIT – I **06 Hours**

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

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

- **Function***:*
  Real Valued function, Classification of real valued functions,

- **Limits and continuity:**
  Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ definition) , $\lim_{x\to a}\frac{x^n - a^n}{x-a} = na^{n-1}$, $\lim_{\theta\to 0}\frac{\sin\theta}{\theta} = 1,$

UNIT –II **06 Hours**

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

UNIT – III **06 Hours**

- **Calculus**
  Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two

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

UNIT – IV **06 Hours**

- **Analytical Geometry**

Introduction: Signs of the Coordinates, Distance formula,

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

Integration:

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

UNIT-V **06 Hours**

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

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

Recommended Books (Latest Edition)

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

Semester II

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

45 Hours

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

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

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

Course Content:

Unit I **10 hours**

- **Nervous system**

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

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

Unit II **06 hours**

- **Digestive system**

  Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.
- **Energetics**

  Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

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

  Anatomy of respiratory system with special reference to anatomy of lungs,

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

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

Unit IV **10 hours**

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

Unit V **09 hours**

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

- **Introduction to genetics**
  Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

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

Reference Books:

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

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

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

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

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound
5.

Course Content:

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

UNIT-I **07 Hours**

- **Classification, nomenclature and isomerism**
  Classification of Organic Compounds
  Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds)
  Structural isomerisms in organic compounds

UNIT-II **10 Hours**

- **Alkanes*, Alkenes* and Conjugated dienes***
  SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP^2 hybridization in alkenes
  E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.
  Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III **10 Hours**

- **Alkyl halides***
  SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.
  SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

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

UNIT-IV **10 Hours**

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

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

UNIT-V **08 Hours**

- **Carboxylic acids***
  Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester
  Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

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

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

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

Recommended Books (Latest Editions)

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

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

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

Objectives: Upon completion of course student shell able to

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

Course Content:

UNIT I **08 Hours**

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

- **Bioenergetics**
  Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.
  Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT **10 Hours**

- **Carbohydrate metabolism**
  Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**
  Electron transport chain (ETC) and its mechanism.
  Oxidative phosphorylation & its mechanism and substrate phosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers level

UNIT III **10 Hours**

- **Lipid metabolism**
  β-Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization

of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid) Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**
  General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disordersCatabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia) Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 Hours**

- **Nucleic acid metabolism and genetic information transfer**
  Biosynthesis of purine and pyrimidine nucleotides
  Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome
  Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis
  Genetic code, Translation or Protein synthesis and inhibitors

UNIT V **07 Hours**

- **Enzymes**
  Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot) Enzyme inhibitors with examples Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

BIOCHEMISTRY (Practical)

4 Hours / Week

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

Recommended Books (Latest Editions)

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

BP 204T.PATHOPHYSIOLOGY (THEORY)

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.

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

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

Course content:

Unit I **10Hours**

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

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

Unit II **10 Hours**

- **Cardiovascular System:**
  Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:** Asthma, Chronic obstructive airways diseases.
- **Renal system:** Acute and chronic renal failure.

Unit II **10 Hours**

- **Haematological Diseases:**
  Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric

disorders: depression, schizophrenia and Alzheimer's disease.

- **Gastrointestinal system:** Peptic Ulcer

Unit IV **8 Hours**

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout
- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis Urinary tract infections
- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

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

Recommended Journals

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

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

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

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

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

Course content:

UNIT – I **06 hours**

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

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

UNIT –II **06 hours**

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

UNIT – III **06 hours**

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT – IV **06 hours**

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

UNIT-V **06 hours**

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

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

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

Recommended books (Latest edition):

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

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

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

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

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

Course content:

Unit-I **10 hours**

The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources:
Natural resources and associated problems

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

Unit-II **10 hours**

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 **10 hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, Mc Graw Hill Inc. 480p

5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT I **10 Hours**

- **Benzene and its derivatives**

A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule

B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.

C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction

D. Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II **10 Hours**

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

UNIT III **10 Hours**

- **Fats and Oils**

a. Fatty acids – reactions. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

b. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

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

UNIT V **07 Hours**

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

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

III Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/Phenol/Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid
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Recommended Books (Latest Editions)

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

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

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

UNIT-II **10 Hours**

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 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45 Hours

Scope:

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

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

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

Course content:

Unit I **10 Hours**

Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).
Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.
Evaluation of the efficiency of sterilization methods.
Equipments employed in large scale sterilization. Sterility indicators.

Unit III **10 Hours**

Study of morphology, classification, reproduction / replication and cultivation of Fungi and Viruses. Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions Evaluation of bactericidal & Bacteriostatic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV **08 Hours**

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

classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.

Unit V **07 Hours**

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

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

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

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

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

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

Course content:

UNIT-I **10 Hours**

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

UNIT-II **10 Hours**

- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.
- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III **08 Hours**

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

UNIT-IV **08 Hours**

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

UNIT- V **07 Hours**

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

Recommended Books: (Latest Editions)

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

BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

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

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT-I **10 Hours**

Stereo isomerism

Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers Reactions of chiral molecules Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute

UNIT-II **10 Hours**

Geometrical isomerism Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) Methods of determination of configuration of geometrical isomers. Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.
Stereospecific and stereoselective reactions

UNIT-III **10 Hours**

Heterocyclic compounds:

Nomenclature and classification Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV **8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole.
Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V **07 Hours**

Reactions of synthetic importance

Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT- I **10 Hours**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

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

Drug metabolism

Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II **10 Hours**

Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

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

Adrenergic Antagonists:

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

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol,

Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III

10 Hours

Cholinergic neurotransmitters:
Biosynthesis and catabolism of acetylcholine.
Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

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

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

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

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

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

UNIT- IV **08 Hours**

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem
Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital
Miscelleneous:
Amides & imides: Glutethmide.
Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

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

hydrochloride.
Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.
Fluro buterophenones: Haloperidol, Droperidol, Risperidone.
Beta amino ketones: Molindone hydrochloride.
Benzamides: Sulpieride.

C. **Anticonvulsants:** SAR of Anticonvulsants**,** mechanism of anticonvulsant action
Barbiturates: Phenobarbitone, Methabarbital. **Hydantoins:**
Phenytoin*, Mephenytoin, Ethotoin **Oxazolidine diones:**
Trimethadione, Paramethadione **Succinimides:**
Phensuximide, Methsuximide, Ethosuximide* **Urea and monoacylureas**: Phenacemide, Carbamazepine* **Benzodiazepines**: Clonazepam
Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V **07 Hours**

Drugs acting on Central Nervous System

General anesthetics:

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

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

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

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

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

BP406P. MEDICINAL CHEMISTRY – I (Practical)

I **4 Hours/ Preparation of drugs/ intermediates**

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

II **Assay of drugs**

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

III **Determination of Partition coefficient for any two drugs Week**

IV

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **07 Hours**

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

UNIT-II **10 Hours**

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

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

UNIT-III **10 Hours**

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

UNIT-IV **10 Hours**

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

UNIT-V **10 Hours**

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

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

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

Recommended Books: (Latest Editions)

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

BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

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

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

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

Course Content:

UNIT-I **08 hours**

1. General Pharmacology

a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

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

UNIT-II **12 Hours**

General Pharmacology

a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.

b. Adverse drug reactions.

c. Drug interactions (pharmacokinetic and pharmacodynamic)

d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharma covigilance.

UNIT-III **10 Hours**

2. Pharmacology of drugs acting on peripheral nervous system

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

UNIT-IV **08 Hours**

3. Pharmacology of drugs acting on central nervous system

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

UNIT-V **07 Hours**

3. Pharmacology of drugs acting on central nervous system

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

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

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

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

Recommended Books (Latest Editions)

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

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacognosy:

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

Classification of drugs:

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

Quality control of Drugs of Natural Origin:

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

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

UNIT-II **10 Hours**

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

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

Conservation of medicinal plants

UNIT-III **07 Hours**

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT IV **10 Hours**

Pharmacognosy in various systems of medicine:

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

Introduction to secondary metabolites:

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

UNIT V **08 Hours**

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

Plant Products:

Fibers - Cotton, Jute, Hemp
Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:
Carbohydrates: Acacia, Agar, Tragacanth, Honey
Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).
Lipids (Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax
Marine Drugs: Novel medicinal agents from marine sources

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

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

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

SEMESTER V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT- I **10 Hours**

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody **H_1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium
H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin
Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate **Miscellaneous:** Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

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

Diuretics:
Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol

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

UNIT- III **10 Hours**

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

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

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

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

UNIT- IV **08 Hours**

Drugs acting on Endocrine system
Nomenclature, Stereochemistry and metabolism of steroids

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

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

UNIT – V **07 Hours**

Antidiabetic agents:
Insulin and its preparations Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

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

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

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

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 502 T. Industrial PharmacyI (Theory)

45 Hours

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

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

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

Course content:

3 hours/ week

UNIT-I **07 Hours**

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

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

b) ***Chemical Properties:*** Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant. Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II **10 Hours**

Tablets:

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

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

UNIT-III **08 Hours**

Capsules:

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

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

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

UNIT-IV **10 Hours**

Parenteral Products:

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

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

UNIT-V **10 Hours**

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

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

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

BP 506 P. Industrial PharmacyI (Practical)

4 Hours/week

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

Recommended Books: (Latest Editions)

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

BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 hours**

1. Pharmacology of drugs acting on cardio vascular system

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

UNIT-II **10 hours**

1. Pharmacology of drugs acting on cardio vascular system

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

2. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

UNIT-III **10 hours**

3. Autocoids and related drugs

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

Recommended Books (Latest Editions)

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

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

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

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

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

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

Benylpropanoids and Flavonoids: Lignans, Tea, Ruta

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

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

Tannins: Catechu, Pterocarpus

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

Glycosides: Senna, Aloes, Bitter Almond

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

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

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

UNIT-IV **10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V **8 Hours**

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

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
   a. Caffeine - from tea dust.
   b. Diosgenin from Dioscorea
   c. Atropine from Belladonna
   d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh
7.

Recommended Books: (Latest Editions)

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

Text Book of

13. Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties**.** Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

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

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

UNIT-III **10 Hours**

- **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions

of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **07 Hours**

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

Recommended books: (Latest Edition)

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

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT – I **10 Hours**

Antibiotics

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

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

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **10 Hours**

Antibiotics

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

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

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

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV **08 Hours**

Antifungal agents:

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

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

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

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

Sulphonamides and Sulfones

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

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

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

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

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

II Assay of drugs

1. Isonicotinic acid hydrazide
2. Chloroquine
3. Metronidazole
4. Dapsone
5. Chlorpheniramine maleate

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

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 hours**

1. Pharmacology of drugs acting on Respiratory system

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

2. Pharmacology of drugs acting on the Gastrointestinal Tract

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

UNIT-II **10 hours**

3. Chemotherapy

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

UNIT-III **10 hours**

3. Chemotherapy

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

g. Antiamoebic agents

UNIT-IV **08 hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

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

UNIT-V **07 hours**

5. Principles of toxicology

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

c. General principles of treatment of poisoning

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

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

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

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

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

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

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

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

Course content:

UNIT-I **11 Hours**

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-II **7 Hours**

Nutraceuticals

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

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

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

UNIT-III **10 Hours**

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

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

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

UNIT- IV **10 Hours**

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

Patenting and Regulatory requirements of natural products:

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

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

UNIT-V **07 Hours**

General Introduction to Herbal Industry
Herbal drugs industry: Present scope and future prospects.
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

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

Recommended Books: (Latest Editions)

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

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS
(Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Introduction to Biopharmaceutics

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

UNIT- II **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, $T^{1/2}$, Vd, AUC, Ka, 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 mainetnance doses and their significance in clinical settins.

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

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

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope: Biotechnology has a long promise to revolutionize the biological sciences and technology.

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

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

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

Unit I **10 Hours**

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

Unit II **10 Hours**

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

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

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

Unit IV **08Hours**

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

Unit V **07 Hours**

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

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP 606 TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

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

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

Course content:

UNIT – I **10 Hours**

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

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

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

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

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

NABL accreditation: Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

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

UNIT – III **10 Hours**

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

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles,

Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

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

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

UNIT – V **07 Hours**

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

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

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

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

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

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.
Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.
Applications-Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

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

UNIT –II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations
Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III **10 Hours**

Introduction to chromatography

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

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

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

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

UNIT –IV **08 Hours**

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

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

UNIT –V **07 Hours**

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

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

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

Recommended Books (Latest Editions)

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

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

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

UNIT-II **10 Hours**

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

UNIT-III **10 Hours**

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

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

UNIT-IV **08 Hours**

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

UNIT-V **07 Hours**

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

Recommended Books: (Latest Editions)

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

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

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

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

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

Unit I: **10 Hours**

a) Hospital and it's organization

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

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

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

d) Community Pharmacy

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

and wholesale drug store.

Unit II: **10 Hours**

a) Drug distribution system in a hospital
Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

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

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

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

e) Patient medication history interview
Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management
Financial, materials, staff and infrastructure requirements.

Unit III: **10 Hours**

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

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

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

d) Education and training program in the hospital
Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the

interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

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

Unit IV **8 Hours**

a) Budget preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

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

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

c) Over the counter (OTC) sales

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

Unit V **7 Hours**

a) Drug store management and inventory control

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

b) Investigational use of drugs

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

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

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

Publishers & Distributers; 2008.
7.

Journals:

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

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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

Objectives: Upon completion of the course student shall be able

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

Course content:

Unit-I **10 Hours**

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

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

Unit-II **10 Hours**

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

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

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

Unit-III **10 Hours**

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

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

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

Unit-IV **08 Hours**

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

Unit-V **07 Hours**

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

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

Recommended Books: (Latest Editions)

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

Journals

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

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

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

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

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

Unit-I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

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

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

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

Unit-II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples **Probability:**Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

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

Unit-III **10 Hours**

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

Introduction to Research: Need for research, Need for design of Experiments,

Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV **8 Hours**

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7 Hours**

Design and Analysis of experiments:

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

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

Recommended Books (Latest edition):

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

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

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

Objectives:

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

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

Course content:

Unit I: **10 Hours**

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

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

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

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

Unit II: **10 Hours**

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

Unit III: **10 Hours**

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: **08 Hours**

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

Unit V: **07 Hours**

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

Recommended Books (Latest edition)*:*

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

Recommended Journals:

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

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

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

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

Unit I **10 Hours**

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

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

Unit II **10 Hours**

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

Unit III **10 Hours**

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

Unit IV **10 Hours**

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

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

Unit V **10 Hours**

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

Emerging concepts in marketing:
Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

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

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

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

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

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

Course content:

Unit I **10 Hours**

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 **10 Hours**

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 **10 Hours**

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 **08 Hours**

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 **07 Hours**

Regulatory Concepts

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

Recommended books (Latest edition):

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

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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

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

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

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

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

Introduction to adverse drug reactions

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

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

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

Unit III **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- clinical investigations

Communication in pharmacovigilance

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

Unit IV **8 Hours**

Safety data generation

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

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH

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

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

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

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice-Essential Concepts and Skills:G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
    http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
12. http://www.ich.org/
13. http://www.cioms.ch/
14. http://cdsco.nic.in/
15. http://www.who.int/vaccine_safety/en/
16. http://www.ipc.gov.in/PvPI/pv_home.html

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

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

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

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

Unit I **10 hours**

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

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.
WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

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

Unit IV **08 hours**

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

Unit V **07 hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

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

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development
Stages of drug discovery and development

Lead discovery and Analog Based Drug Design
Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

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

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)
SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

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

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

UNIT-IV **08 Hours**

Informatics & Methods in drug design

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

UNIT-V **07 Hours**

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

Recommended Books (Latest Editions)

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

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

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 organismssuch as humans, plants, and sponges.

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

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

Course content:

Unit I **10 Hours**

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

Unit II **10 Hours**

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

Unit III **10 Hours**

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

Unit IV **08 Hours**

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

Unit V **07 Hours**

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

Recommended Books (latest edition):

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

BP809ET. COSMETIC SCIENCE (Theory)

45 Hour

UNIT I **10 Hours**

Classification of cosmetic and cosmeceutical products
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs
Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application
Skin: Basic structure and function of skin.
Hair: Basic structure of hair. Hair growth cycle.
Oral Cavity: Common problem associated with teeth and gums**.**

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:
Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

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

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.
Role of herbs in cosmetics:
Skin Care: Aloe and turmeric Hair care: Henna and amla.

Oral care: Neem and clove
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste**.**

UNIT IV **08 Hours**.

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

UNIT V **07 Hours**

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

body odor.
Antiperspirants and Deodorants- Actives and mechanism of action

References

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

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

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

Objectives

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

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

Unit –I **08 Hours**

Laboratory Animals:

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

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

Unit –II **10 Hours**

Preclinical screening models

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

b. Study of screening animal models for

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

Unit –III

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

Unit –IV

Preclinical screening models: for CVS activity- antihypertensives, diuretics,

antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants
Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

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

Selection of research topic, review of literature, research 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

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy
Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications
Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

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

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X- ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT-III **10 Hours**

Calibration and validation-**as per ICH and USFDA guidelines**
Calibration of following Instruments
Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **08 Hours**

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

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

UNIT-V **07 Hours**

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

Recommended Books (Latest Editions)

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

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours: 3 **Tutorial:1** **Credit point:4**

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

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

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

UNIT I **07 hours**

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.

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

c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II **15 hours**

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

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

UNIT III **07 hours**

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

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

UNIT IV **10 hours**

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

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

c) Functional foods for chronic disease prevention

UNIT V **06 hours**

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

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

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

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

Semester VIII – Elective course on Pharmaceutical Product Development

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

Unit-I **10 Hours**

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

Unit-II **10 Hours**

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

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

Unit-III **10 Hours**

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

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

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

Unit-IV **08 Hours**

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

Unit-V **07 Hours**

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

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third

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

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IIMT College of Medical Sciences (Pharmacy)

ACADEMIC HAND BOOK

Scheme & Syllabus

Master of Pharmacy (M. Pharm.)

Course

CHAPTER –I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

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

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

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

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

9. Course of study

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

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

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

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

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

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

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

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

Table – 4: Course of study for M. Pharm. III Semester (Common for all Specializations)

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

* Non University Exam

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

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

Table – 6: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

Table – 7: Guidelines for Awarding Credit Points for Co-curricular Activities

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

Note: International Conference: Held outside India

International Journal: The Editorial Board outside India

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

10. Program Committee

1. The M. Pharm. programme shall have a programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the programme Committee:

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

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table–16. End semester examinations.

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol

(*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables –8: Schemes for internal assessments and end semester (Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
SEMESTER II								
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH 205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total	650							

Schemes 9 for internal assessments and end semester (Pharmaceutical Chemistry)

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

Tables – 10: Schemes for internal assessments and end semester examinations (Semester III & IV)

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

*Non University Examination Internal assessment: Continuous mode

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

Table –11: Scheme for awarding internal assessment: Continuous mode

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

Table – 12: Guidelines for the allotment of marks for attendance

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

11.2.1. **Sessional Exams**

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

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Re-examination of end semester examinations

Re-examination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 13: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances

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 – 30.

Table – 14: 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 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

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

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

19. Cumulative Grade Point Average (CGPA)

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

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

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,…is the SGPA of semester I,II,III,…. .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows: First Class with Distinction = CGPA of. 7.50 and above

First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

21. Project work:

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

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

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	**500 Marks**

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	**250 Marks**

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation/retotaling of answer papers

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

26. Re-admission after break of study

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

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope

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

Objectives

After completion of course student is able to know,

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

S. No.	THEORY	60 HOURS
1.	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy. b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	11 Hrs
2.	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy\	11 Hrs
3.	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	11 Hrs
4.	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
5.	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors	11 Hrs

	affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	
b)	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5 Hrs

Reference:

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

DRUG DELIVERY SYSTEMS (MPH 102T)

SCOPE

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

OBJECTIVES

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

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

S. No.	THEORY	60 Hrs
1.	Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2.	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3.	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4.	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
5.	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6.	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7.	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by 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) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH 103T)

Scope

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

Objectives

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

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

S.No.	THEORY	60 HRS
1.	a) Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	10 Hrs
	b) Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10 Hrs
2.	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3.	CGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10 Hrs
4.	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5.	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.

8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH 104T)

Scope

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

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

Objectives:

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

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

	THEORY	**60 Hrs**
1.	a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	12 Hrs
2.	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3.	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4.	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.

Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard 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. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I (MPH 105P)

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

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

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

S.No.	THEORY	60 Hrs
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2.	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3.	Micro Capsules/Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4.	Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5.	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Bio distribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

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

Objectives

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

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

S.No.	THEORY	60 Hrs
1.	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	12 Hrs
2.	Bio pharmaceutics considerations in drug product design and In Vitro Drug Product Performance: Introduction, bio pharmaceutics factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	12 Hrs
3.	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment-model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein- binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.	12 Hrs

4.	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5.	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES

a) Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
b) Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
c) Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
d) Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
e) Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
f) Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
g) Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Row land and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
h) Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
i) Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
j) Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
k) Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
l) Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
m) Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Scope

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

Objectives

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

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

	THEORY	60 Hrs
1.	a) Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b) Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12 Hrs
2.	Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs
3.	Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	12 Hrs
4.	a) Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations b) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c) Computers in Clinical Development: Clinical Data Collection and	12 Hrs

	Management, Regulation of Computer Systems	
5.	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

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

COSMETICS AND COSMECEUTICALS (MPH 204T)

Scope

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

Objectives

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

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

	THEORY	**60 Hrs**
1.	Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12 Hrs
2.	Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12 Hrs
3.	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed Controversial ingredients: Parabens, formaldehyde liberators, dioxane, as allergens in EU regulation.	12 Hrs
4.	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12 Hrs
5.	Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition

4. Handbook of cosmetic science and Technology A.O. Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II (MPH 205P)

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

PHARMACEUTICAL CHEMISTRY (MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

Scope

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

Objectives

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

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

S.No.	THEORY	60 Hrs
1.	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2.	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 Hrs
3.	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4.	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography	

	h) Affinity chromatography i) Gel Chromatography	
5.	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a. Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10 Hrs
6.	a) Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b) Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10 Hrs

REFERENCES

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

ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

Scope

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

Objectives

Upon completion of course, the student shall be to understand

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

	THEORY	**60 Hrs**
1.	Basic Aspects of Organic Chemistry: Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications. Types of reaction mechanisms and methods of determining them,	12 Hrs
2.	Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Addition reactions a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2) b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) c) Rearrangement reaction	12 Hrs
3.	Study of mechanism and synthetic applications of following named Reactions: Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction	12 Hrs
4.	Synthetic Reagents & Applications: Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). Protecting groups a. Role of protection in organic synthesis b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals c. Protection for the Carbonyl Group: Acetals and Ketals d. Protection for the Carboxyl Group: amides and hydrazides, esters e. Protection for the Amino Group and Amino acids: carbamates and amides	12 Hrs
5.	Heterocyclic Chemistry: Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and	12 Hrs

	Traube purine synthesis. Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline, Mercaptopurine and Thioguanine.	
6.	Synthon approach and retrosynthesis applications i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.	

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.

Organic Reaction Mechanisms IV th Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

Scope

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

Objectives

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

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

S.No.	THEORY	60 Hrs
1.	Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.	12 Hrs
2.	Prodrug Design and Analog design: a) Prodrug design: Basic concept, Carrier linked prodrugs/Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance. Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.	12 Hrs
3.	a) Medicinal chemistry aspects of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: b) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents. c) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.	12 Hrs
4.	Rational Design of Enzyme Inhibitors Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	12 Hrs

5.	Peptidomimetics Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	12 Hrs

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt. Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt. Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Bio pharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

Scope

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

Objectives

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

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

	THEORY	**60 Hrs**
1.	Study of Natural products as leads for new pharmaceuticals for the following class of drugs a) Drugs Affecting the Central Nervous System: Morphine Alkaloids b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol d) Neuromuscular Blocking Drugs: Curare alkaloids e) Anti-malarial drugs and Analogues f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)	12 Hrs
2.	a. Alkaloids General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine. b. Flavonoids Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin. c. Steroids General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adre nocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).	12 Hrs
3.	a) Terpenoids Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene). b) Vitamins Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	12 Hrs
4.	a) Recombinant DNA technology and drug discovery rDNA technology,	12 Hrs

	hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation b) Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, c) Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.	12 Hrs
5.	Structural Characterization of natural compounds Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.	12 Hrs

REFERENCES

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

Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I (MPC 105P)

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

To perform the following reactions of synthetic importance

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

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

Scope

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

Objectives

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

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

	THEORY	**60 Hrs**
1.	UV and IR spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12 Hrs
2.	NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12 Hrs
3.	Mass Spectroscopy Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. Chromatography:	12 Hrs
4.	Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography	12 Hrs
5.	a) Thermal methods of analysis Introduction, principle, instrumentation and application of DSC, DTA and TGA. b) Raman Spectroscopy Introduction, Principle, Instrumentation and Applications. c) Radio immuno assay Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin	12 Hrs

REFERENCES

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

ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)

Scope

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

Objectives

Upon completion of course, the student shall able to understand

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

	THEORY	60 Hrs
1.	Green Chemistry: a. Introduction, principles of green chemistry b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications d. Continuous flow reactors: Working principle, advantages and synthetic applications.	**12 Hrs**
2.	2 Chemistry of peptides a. Coupling reactions in peptide synthesis b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies d. Side reactions in peptide synthesis: Deletion peptides, side	**12 Hrs**
3.	reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.	**12 Hrs**
4.	Photochemical Reactions Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. Pericyclic reactions Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples	**12 Hrs**

5.	3 Catalysis: a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. f. Phase transfer catalysis - theory and applications	**12 Hrs**
6.	Stereochemistry & Asymmetric Synthesis g. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. h. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.	

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.

Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (MPC 203T)

Scope

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

Objectives

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

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

S.No.	Theory	60 Hrs
1.	Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications. Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.	12 Hrs
2.	Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.	12 Hrs
3.	Molecular Modeling and Docking a) Molecular and Quantum Mechanics in drug design. a) Molecular and Quantum Mechanics in drug design.	12 Hrs

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

	In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.	

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

1. Process chemistry **12 Hrs**

Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities

Unit operations 12 Hrs

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

Unit Processes - I

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.

Unit Processes - II

d) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
e) Fermentation: Aerobic and anaerobic fermentation.

Production of

i. Antibiotics; Penicillin and Streptomycin,

ii. Vitamins: B2 and B12
iii. Statins: Lovastatin, Simvastatin

f) Reaction progress kinetic analysis
i. Streamlining reaction steps, route selection,
ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

Industrial Safety

g) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
h) Fire hazards, types of fire & fire extinguishers
i) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management

REFERENCES

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

PHARMACEUTICAL CHEMISTRY PRACTICALS – II (MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. $NaBH_4$ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

Semester III

MRM 301T- Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

IIMT College of Medical Sciences (Pharmacy)

ACADEMIC HAND BOOK

Doctor of Philosophy (Ph.D)

Syllabus for Ph.D. Course Work
(Effective from the Session: 2020-21)

PREAMBLE

IIMT University, Meerut offer academic programmes leading to the award of Ph.D. degree through its schools/colleges. The award of Ph.D. degree is in recognition of high academic achievements, independent research and application of knowledge to the solution of technical and scientific problems in Science, Technology, Humanities & Social Sciences and Management; creative and productive inquiry is the basic concept underlying the research works.

The academic programme leading to the Ph.D. degree is broad-based and involves a prescribed course credit requirement and a research thesis. The university also encourages interdisciplinary areas through a system of Co-supervision and provides excellent opportunities for such programmes. The institute undertakes sponsored research and development projects from industrial and other organization in the public as well as private sector.

The degree of Doctor of Philosophy shall be abbreviated as Ph.D. The Degree of Philosophy is granted for research work in areas recognized by the Academic Departments/Centers of the Institute subject to the conditions and regulations contained hereinafter.

The research work shall be an original work characterized either by the discovery of facts, or by a fresh approach towards the interpretation and application of facts, or development of innovative products and technologies. It shall evince the candidate's capacity for critical examination and sound judgment and shall represent original contribution to the existing knowledge.

The degree of doctor of philosophy (Ph.D.) of the IIMT University, Meerut shall be conferred on a candidate who successfully completes all the requirements specified in these ordinances and regulations, which were approved by Academic Council.

Procedure for Award Doctor of Philosophy (Ph.D.) Degree

1. The Ordinance conforms with University Grants Commission Gazette (Minimum Standards and Procedure for Award of M.Phil./Ph.D. Degrees) Regulations, 2016.
2. If the M.Phil degree is awarded by a Foreign University, the University considering such a degree shall refer the issue to a Standing Committee constituted for the purpose of determining the equivalence of the degree awarded by the foreign University.
3. Part-time Ph.D. will be allowed provided all the conditions mentioned in the extant Ph.D. Regulations are met.

DEFINITIONS

1. **"Applicant"** shall mean an individual who applies for admission to the Ph.D. program of the IIMT University on a prescribed Application Form.

2. **"Caretaker Research Supervisor"** shall mean a member of the academic staff appointed to look after the scholar's research interests in the absence of the Research Supervisor and after the submission of thesis.

3. **"Course Advisor"** shall mean a faculty member nominated by the School/Department/ Centre to chalk-out the program of study of a student registered for the Ph.D. and to advise him on the courses to be taken by him. If a Research Supervisor(s) has already been appointed, he shall ordinarily be the Course Advisor for that student.

4. **"Course Work"** shall mean courses of study prescribed by the School/ Department/Centre through the Course Advisor to be undertaken by a student registered for the Ph.D. Degree.

5. **"Committees"** Shall mean Departmental (includes center's) Research committees (DRC) overseeing the PhD works in the respective department and Research Advisory Committee (RAC) assigned to each scholar for monitoring/mentoring the Ph.D. work and progression.

6. **"Co Supervisor"** shall mean an additional supervisor approved by the Competent Authority on the recommendation of School/Department/Centre.

7. **"Degree"** shall mean the Degree of Doctor of Philosophy (Ph.D.) of the IIMT University.

8. **"Full-time Research Student/Scholar"** shall mean a person registered for the Ph.D. Degree devoting full time for completing the degree requirements.

9. **"University"** shall mean the IIMT University, Meerut.

10. **"Minimum Registration Period"** shall mean the minimum period for which a scholar must be registered, including the time spent as student before becoming a scholar, prior to submission of the thesis.

11. **"Part-time Research Student/Scholar"** shall mean a person who is registered for the Ph.D. degree and will devote part of his time towards this pursuit and devote part of his time towards the discharge of his official obligations.

12. **"Research Supervisor"** shall mean a member of the academic staff of the University approved by Competent Authority on the recommendation of DRC to guide/ supervise the research/ academic work of the student/scholar.

13. **"Registration Period"** shall mean the length of time span commencing with the date of initial registration at the University till the completion of the program.

14. **"Residency"** shall mean the minimum period for which a student/scholar must attend the University on full-time basis.

15. **"Scholar"** shall mean a person registered for the Ph.D. Degree and who has successfully completed the course requirement.

16. **"Student"** shall mean a person registered for the Ph.D. degree prior to becoming a scholar.

17 **"DAIP & IAIP"** shall mean Departmental Academic Integrity Panel and Institutional Academic Integrity Panel.

18. **"HAR"** shall mean the Head, Academic Research.

(Note: 'He' & 'His' where ever they figure in the document shall imply 'he'/'she' and 'his'/'her' respectively.

ELIGIBILITY

1.1. Candidates for admission to the Ph.D. programme shall have a Master's degree or a professional degree declared equivalent to the Master's degree by the corresponding statutory regulatory body, with at least 55% marks in aggregate or its equivalent grade 'B' in the UGC 7-point scale (or an equivalent grade in a point scale wherever grading system is followed) or an equivalent degree from a foreign educational Institution accredited by an Assessment and Accreditation Agency which is approved, recognized or authorized by an authority, established or incorporated under a law in its home country or any other statutory authority in that country for the purpose of assessing, accrediting or assuring quality and standards of education institutions.

1.2 A relaxation of 5% of marks, from 55% to 50%, or an equivalent relaxation of grade, may be allowed for those belonging to SC/ST/OBC (non-creamy layer)/Differently-abled and other categories of candidates as per the decision of the Commission from time to time, or for those who had obtained their Master's degree prior to 19th September, 1991. The eligibility marks of 55% (or an equivalent grade in a point scale wherever grading system is followed) and the relaxation of 5% to the categories mentioned above are permissible based only on the qualifying marks without including the grace mark procedures.

1.3. An employee of a Public Sector Undertaking, a Government Department, a Research/ Development Organization, or a private industry (approved by the Academic Council) or an Educational Institution with a minimum relevant working experience of two years and a Defense Sponsored Officer may be considered for admission as a sponsored full-time/part-time Research scholar. Sponsored applicants will be eligible for admission provided that they are treated by their employers as on duty with their normal salary and allowances and are fully relieved for the period of study. Part-time applicants will be eligible provided that:

(a) The applicant possesses the minimum entry qualifications as given in 1.1 above;
(b) The applicant proves to the satisfaction of the Head Research that his official duties permit him to devote sufficient time to research;
(c) Facilities for research are available at the applicant's place of work in the chosen field of research; and
(d) He is required to reside at the University campus for a period of not less than the time required for course work before his registration for the degree. (This condition of minimum residence may be waived for scholars who are working in Meerut or in organizations/ institutions located within a distance of 100 km from the University, subject to satisfaction of Head Research that he shall be able to attend all classes of the course work even during week days).

1.4. A member of the Academic/Non-Academic staff of the University who satisfies eligibility qualifications may be considered for admission to the Ph.D. degree as a part time student provided he has been given administrative clearance by the Vice Chancellor. Those M.Sc. or equivalent qualification and with less than two years of relevant working experience must have a valid GATE score or must have qualified any other national level examination conducted by those like UGC/CSIR, etc before being considered for administrative clearance.

1.5. Full time project JRFs/SRFs, joining and working in IIMT University in funded R&D projects, may be registered for PhD program, subject to following:

(a) In case he/she qualifies through the entrance procedure as for other students.
(b) For this, if the project funding has already been received and JRF approved as part of project, all aspiring JRFs shall be interviewed by both (i) PhD selection committee (ii) and the JRF selection committee. (iii) Final selection shall be based on priority 1 for students who qualify both for PhD and JRF.
(c) In case only Project sanction has been received and not the funding, the aspiring JRFs, shall be required to wait till funding is received.
(d) Such candidates shall be funded through the project grant. In case the project gets over, before completion of the PhD degree, the student shall be treated as a full time Ph.D. student and governed by Assistantship rules so applicable to regular students.

ADMISSION PROCEDURE

2.1 The entrance test shall be conducted twice in a year and the eligibility of shortlisted candidates shall remain valid for one year.
2.2 The University shall issue notification for Ph.D. admission at the beginning of each Semester in leading newspaper as well as on website of the university. The candidates desirous of registering for Ph.D. Programme shall download the Application Form for Admission from the University website (www.iimtu.com), fill-in all the details along with copies of required documents and submit the same through proper channel, wherever applicable, before the due date as indicated in the notification issued from time to time.
2.3 Incomplete applications in any respect shall be liable to be summarily rejected without any intimation to the candidate.
2.4 The Head- Ph.D programme will send the availability of seats subject wise to the concerned person to notify on website with a notice in newspaper.
2.5 Chairman/DRC shall screen the applications as per the eligibility norms.
2.6 Entrance test will be conducted by Controller of Examination (COE) in consultation with Head-Ph.D.
2.7 After the declaration of successful candidates in written test, DRC will conduct the interview.
2.8 COE will compile the written and interview marks, and will declare the final result.
2.9 Admission fees will be deposited by the candidates in the direction of admission controller.
2.10 The application of the students will be compiled by Head-Ph.D Programme.
2.11 An Entrance Test shall be qualifying with qualifying marks as 50%. The syllabus of the Entrance Test shall consist of 50% of research methodology and 50% shall be subject specific.
2.12 An interview/viva-voce to be organized to discuss their research interest/area through a presentation before a duly constituted Department Research Committee.
2.13 The interview/viva-voce shall also consider the following aspects, viz. whether: the candidate possesses the competence for the proposed research; the research work can be suitably undertaken at the Institution/College; the proposed area of research can contribute to new/additional knowledge.
2.14 For final selection of candidate a weightage of 70% to the entrance test and 30 % to the interview/viva-voce shall be given.
2.15 Candidates qualified with M.Phil./GATE/NET/SLET/other National Level Eligibility Test OR working in recognized Universities/Institutes/Research centers having hands on

research experience and having the evidence of published research work can be exempted from written test and but have to appear for the interview only.

2.16 On the recommendation of DRC and Head Research, Vice Chancellor shall approve the short listed candidates for admission to the doctoral programme in the appropriate specialization, after giving due consideration to the interdisciplinary fields of research, if any, and decide the Faculty in which the candidate shall be registered.

2.17 Selected candidates shall be provisionally registered for Ph.D. programme with the approval of the Vice-Chancellor either in February or July session.

CLASSIFICATION OF RESEARCH SCHOLAR

3.1. The applicants for admission to the Ph.D. program shall be classified under any one of the following categories:

(a) **University's Research student/scholar (Full Time).** They shall be working full time in the University and also may be in receipt of Ph.D Assistantship awarded by the university or an outside agency like DST/DBT/CSIR etc.

(b) **Sponsored Research student/scholar.** Those financed by the Government/Semi-Government Organizations like CSIR, UGC, and Research Schemes etc or nominated by Government of India under a Cultural Exchange Scholarship Program, Self-Financing foreign student/scholar or those admitted under an MOU may be admitted as full time scholars without Assistantship. Those who are working in the industry / institutions and are spared/sponsored by their parent organization full time, for doing the Ph.D. work shall also come under the sponsored category. Such scholars will have to provide the required undertaking from their sponsoring organization. (Performa as per Annexure-1).

(c) **Part-time Research student/scholar.** They may include University faculty/staff, project staff like JRF etc. who are on rolls of the University and working under the project supervisors for various sponsored projects if the duration of the Project at the time of admission is around 3 years. Further, scholars who may be working elsewhere and willing to meet the Ph.D program progression requirements like residential requirement/ course work and following requirements-

i. The applicant is required to reside at the institute for a period till he/she is admitted for candidacy (This condition of minimum residency period will be automatically waived for candidates who are working in IIMT University or in organizations/institutions located within a distance of 100 KM from the university).
ii. The applicant proves that his official duties permit him to devote sufficient time to research.
iii. The applicant must have been in continuous service with the sponsoring organization for at least two years at the time of registration.

Note- The University may be enrolled as a part time students/scholars (in the School/ Departments which may offer part time programs) subject to production of a "No

Objection Certificate" (proforma as per Annexure-2) from their organization and after satisfying above requirements.

3.2. For Conversions of various classifications of scholars permission of Competent Authority is essential and which shall be granted only after following rules are compiled:

(a) A full-time scholar may be allowed by Head Research to convert his registration into part-time registration only after completion of at least 2 years, if the scholar is having M.Tech./M.Phil qualification, and 3 years if the scholar does not have-M.Tech./M.Phil qualification or after comprehensive examination or after submission of synopsis or, if he gets employed in the University's Sponsored Projects.

(b) Full-time Ph.D. Scholars in the Science Departments with M.Sc. qualifications can be permitted to convert their registration from full-time to part time after two years or after completion of course work and comprehensive examination, whichever is later, if they get employed in the University's Sponsored Projects.

(c) Such conversion will be permissible only if the work is in the Projects of the University, and not for employment outside.

3.3. If a part-time Ph.D. student applies for conversion of his registration into full-time, the Head Research, on recommendation of DRC, may allow him the same either with or without assistantship on the merits of each case provided:

(a) On the date of application the student has satisfied all conditions prescribed for admission as a full-time student.

REGISTRATION

4.1 The candidates are required to give their choice for supervisors based on their choice for supervisors based on his/her area of interest and the supervisor is allocated to him/her at the time of recommending the candidates for admission. The candidates shall be informed about the supervisor allocated in the admission letter. The candidate shall have to work with the supervisor allocated.

4.2 Every student/scholar is required to register himself/herself (in person) on the scheduled dates of registration (only). There shall not be any provision of deputing any representatives by him/her for registration purposes. Further, he/she shall be required to register in subsequent semesters till the submission of Ph.D. thesis.

4.3 Every student/scholar will be required to renew the registration every Semester till the submission of the thesis. The renewal of registration every Semester shall be subject to completion of specified number of credits/courses and/or satisfactory progress in his research work as recommended by Research Advisory Committee (RAC).

4.4 Every student/scholar is required to fill the registration form and deposit it with the department through his/her supervisor(s).

4.5 Every student/scholar shall be allowed to register for the subsequent semester(s)if his/her progress report by his/her supervisor(s) HOD during the previous semester(s) is found satisfactory.

4.6 The act of not-depositing the fee or not-completing the registration process as mentioned above on the scheduled dates shall be treated as the "voluntary discontinuation" of studies by the Research Scholar. In such case, he/she will cease to be a bonafide student with immediate effect.

4.7 The instructions as above for registration shall be applicable for all full-time and part-time Research Scholars.

4.8 Late registration will be with a late fee of Rs. 500/- up to one week beyond the last date specified for the registration. However under special circumstances, the period may be relaxed by the Competent Authority.

4.9 Every student/scholar is required to follow the registration rules till he/she submits his/her Ph.D. thesis.

4.10 In case a student wishes to temporarily withdraw from his Ph.D. program, he may do so only after a period of two years following his date of confirmation of Registration with prior permission of the Vice-Chancellor. The application for temporary withdrawal must be endorsed by the RAC. Duration of temporary withdrawal beyond the period of one year would normally not be encouraged, and may be granted by the Vice Chancellor on recommendation by the DRC only under circumstances considered to be genuinely extraordinary. The period of temporary withdrawal will not be counted, when counting the number of Terms/ semesters of Ph.D. registration already completed by the student.

4.11 If a student/scholar withdraws from his Ph.D. Program or his registration is terminated, his student/ scholar status shall cease. If such a student/ scholar is re-admitted, he may be given weightage to the credits acquired during the previous registration on the recommendation of the DRC, except in the case of termination on disciplinary grounds.

4.12. Any student who concurrently registers for any postgraduate degree (registration for on line or part time certification courses is excluded) at another organization shall be automatically de-registered at the University.

COURSE WORK

5.1. On joining the University every student is required to plan his academic program in consultation with his course advisor/research supervisor/RAC if already nominated.

All students in the Ph.D. program are required to acquire the prescribed credits through course work, which shall normally be completed as per specified time duration for respective program.

5.2. The courses offered for the Ph.D. Programs may be: Lecture Courses, Laboratory Courses, Design Courses, Seminars, Courses pertaining to communication skills, research methodology, literature survey etc. The credit for a course depends upon the contact hours and self-study hours associated with it and duly approved by the BOS.

5.3. All Ph.D. students are to compulsorily register in some essential courses as may be specified at the time of registration/renewal of registration for the Ph.D. research work till they submit the thesis. Each student will be required to take course work as prescribed by

the research supervisor(s)/ course advisor/RAC. Ph.D. students will be allowed to complete extra credit courses, if necessary.

5.4. For all course work students shall be governed by the rules and regulations for the level of courses as per respective departments. The coursework shall be transferable between the departments of the university and interuniversity subject to their acceptance by RDCU.

5.5. The minimum overall CGPA requirement in course work shall be 6 on a 10 point scale (or 55%) for student to be accepted as scholar for Ph.D. Degree. If the CGPA of any student is below 6.00, at the end of any semester, his registration will be terminated with immediate effect, provided the additional allowed time.

5.6. Notwithstanding the above Regulations, the RAC may consider giving credit to the courses already completed/passed by a scholar at the University, as a part of his any earlier Ph.D. registration.

5.7. (a) The credit assigned to the Ph.D. coursework shall be a minimum of 08 credits and a maximum of 16 credits.

(b) The coursework shall be treated as prerequisite for Ph.D. preparation. A minimum of 4 credits shall be assigned to one or more courses on Research Methodology which could cover areas such as quantitative methods, computer applications, research ethics, and review of published research in the relevant field, training, field work etc. Other courses shall be advanced level courses preparing the students for Ph.D. degree.

(c) All candidates admitted to the Ph.D. programmes shall be required to complete the course work prescribed by the department during the initial one or two semesters.

RESEARCH SUPERVISOR(S) / RESEARCH COMMITTEES

6.1 Every admitted student shall be assigned a Research Supervisor(s) by the Head of the Department on the recommendations of the DRC, subject to approval of the Vice-Chancellor. Allocation of Research supervisor shall be decided by the DRC depending upon the number of scholars per supervisor, available specialization, research interest of the student etc.

6.2 Research Advisory Committee (RAC) for each PhD Scholar should constitute in the beginning of 1st semester and should define tentative research plan along with courses to be done. The courses should be aligned to research plan of the PhD scholar. The RAC for a research student shall be appointed within a week but not later than a month from the date of admission by the competent authority.

6.3 The Head Research on the recommendations of the DRC may appoint co-supervisor(s) not exceeding a total of two supervisors per student/scholar considering the nature of the research topic, who should fulfill the same condition of having PhD, as the main Supervisor. In exceptional cases where the research topic is of interdisciplinary nature, Head Research may approve a third supervisor. Co-supervisors may be from inside or outside the University.

6.4 **Contingencies in Appointment of Research Supervisors/co-Supervisors and Caretaker-research Supervisor for Ph.D. students.**

A faculty member appointed as a Ph.D. supervisor is normally expected to be available to a research scholar in the University till the thesis Viva is held. However, under unavoidable circumstances, such as long leave of more than 12 months; resignation; retirement; or death; a supervisor may not be available to the scholar. In such special cases, appointment of supervisor(s) will be regulated as under:

(a) A supervisor proceeding on long leave of more than 12 months

i. Where co supervisor exists, the supervisor proceeding on long leave for more than 12 months can continue to be a co supervisor provided the DRC is convinced of effective supervision by the co -supervisor.

ii. Where a co -Supervisor does not exist, a co-supervisor may be appointed by the DRC in cases where a student has not yet submitted his synopsis.

iii. Provided, if the synopsis of the thesis has been submitted before the supervisor proceeds on leave, he will continue to be the supervisor and only a caretaker research supervisor will be appointed.

iv. Further, if a major revision becomes necessary, and the sole supervisor is on leave, he should be asked to specifically state whether he would effectively help the student carrying out the major revisions within a reasonable time. In case the sole supervisor expresses his inability due to one reason or the other, the caretaker supervisor, if he provides the required help in carrying out the major revision, will automatically be treated as co -Supervisor of that scholar.

v. Provided further, if a supervisor proceeds on leave for a period less than 12 months initially, but later extends his leave beyond 12 months, the above procedure will be followed.

(b) A Supervisor retires.

A faculty member who is due to retire within the next two years can be appointed as a co-supervisor and can continue to be the co Supervisor even after his retirement provided the DRC is convinced of his availability/continued guidance to the student. In other cases, a faculty member on retirement may continue as

i. a supervisor, if reemployed or appointed Emeritus Fellow;

ii. a co-supervisor, if the synopsis of the thesis has been submitted. Appointment of another supervisor, if necessary, will be as per a (i); and caretaker Supervisor as per a(ii).

(c) **A Supervisor resigns**

A new Supervisor will be appointed, if necessary, as per a (i), and a caretaker supervisor as per a(ii).

(d) **A Supervisor dies**

A new Supervisor will be appointed, if necessary, on the recommendation of DRC.

(e) Change of Supervisor (s) under exceptional circumstances shall be permitted on recommendation of the DRC with the consent of (i) the student, (ii) the present Supervisor (s), and (iii) the proposed supervisor (s).

(f) If the research program and/or area of the work require modification due to this change, the student's entire course program requirement shall be examined by the DRC. If there is change in the research program and/or area of the work, the registration date may be revised, if found necessary.

Subject to the general superintendence of the Academic Council, the following Committees shall deal with all the matters connected with the Ph.D. Programmes of the university in accordance with these ordinances;

a) The Research Degree Committee of University (RDCU)
b) Research Advisory Committee (RAC)
c) Departmental Research Committee (DRC)

6.5 RDCU (Research Degree Committee of University)

RDCU shall ensure uniform implementation of the Ordinance and provide advice on procedural and related matters. The composition of RDC shall include the following-

1.	VC	**(Chairperson)**
2.	Dean-Research	(**Member)**
3.	Chairman, DRC;	(**Member)**
4.	Head of the Department	(**Member)**
5.	Two Professors other than Supervisors	(**Member)**
6.	Supervisor(s) or co-supervisors.	(**Member(s))**
7.	Head Ph.D.	**Member Secretary**

RDCU shall have the following responsibilities;

The Committee shall–

(a) suggest measures to create links and develop specific schemes of inter-university and University interaction with industry, agriculture, banks, commerce and community etc.;

(b) prepare University perspective development plans, both short-term and long-term, keeping in view the objectives of the University provided in this Act, and with due regard to the State and National Educational, requirement;

(c) recommend to the Executive Council the research and development and collaborative programmes for the University;

(d) Monitor and report the progress of all such approved research and development and collaborative programmes to the Chancellor once a year;

(e) evaluate and assess the use of research and development grants by University, and submit the report to the Executive Council;

(f) shall approve Research Advisory Committee (RAC) for Ph.D.'s as recommended by various academic departments/center/units of University;

(g) organize research and development audit and prepare report thereof for University and also to maintain research and development data of University on session basis

according to the provisions of the Statutes, and make necessary recommendations to the Academic Council/Executive Council, as applicable, for implementation;

(h) scrutinize the applications received for Patents and IPRs received from teachers and students of University.

(i) The supervisors and Co-Supervisors will be approved by RDCU on the recommendations of DRC.

6.6. **Research Advisory Committee (RAC)**

RAC shall be duly constituted by competent authority for every scholar and generally comprise of following:

1. Chairman, DRC; **(Chairperson)**
2. One expert in the field from the Department/Centre; **(Member)**
3. One expert preferably in the concerned area, from outside the University to which the student belongs; **(Member)**
4. Supervisor(s) or co-supervisors. **(Convener)**

Experts at (3) and (4) above will be nominated by VC from amongst those proposed by DRC.

RAC shall have following responsibilities

(a) Identify the course(s) that he/she may do.

(b) To guide the scholar to study, develop and design the methodology of research.

(c) To review the research proposal and finalize topic of research and,

(d) To periodically review and assist in the Progress of research work of scholar.

(e) The supervisors or Co-Supervisors for students will be approved by RAC on the recommendations of DRC.

Note- Once approved, the members of RAC can be changed only under exceptional circumstances on recommendations from the department by competent authority. All committee members are required to be Ph.D holders.

6.7. **Departmental Research Committee (DRC)**

There shall be a Departmental Research Committee (**DRC)** to oversee the process and progress of academic research activities for every department/ School/College level.

Composition of DRC

1. Dean of College/School **(Chairperson)**
2. Head College/School **(Member Secretary)**
3. All Professors of the Department **(Member)**
4. Professor (Member from outside the Department/school/College) **(Member)**
5. Associate professor/Assistant Professor **(Member)**
6. Supervisors/Co supervisors **(Member)**

Functions of DRC (Departmental Research Committee)

(a) To conduct viva-voce/interview of student, where the committee checks the eligibility and the research competence of the candidate.

(b) The allocation of research supervisor for a selected research scholar shall be decided by the DRC depending on the number of scholars per research supervisor, the available specialization among the supervisors and research interests of the scholars as indicated by them at the time of interview/viva-voce.

(c) A student already holding a M.Phil degree with at least 55% marks or 7 CGPA can be exempted from course work on the recommendations of DRC.

(d) Grades in the course work, including research work methodology course shall be finalized after a combined assessment by the RAC and DRC and final grades shall be communicated to the School/college.

Oral/Seminar

7.1. Oral/ Seminars shall satisfy the following conditions:

(a) Seminar in a semester shall be of two credits and every research student must deliver a seminar as a part of course requirement and beyond the minimum limit of credits for course requirement.

(b) Seminar shall be treated as additional course for the purpose of registration and evaluation.

(c) Supervisor shall act as seminar coordinator and decide the topic of seminar in accordance with the area of research. Supervisor shall arrange the seminar and forward the grade awarded by the DRC to the competent authority by the end of the semester.

(d) A student shall not get credits for more than one Seminar during the entire Ph.D programme.

(e) All research scholars/students are required to be adjudged for proficiency in English while delivering seminar which is mandatory for everyone. The DRC will give its recommendation along with the result of seminar whether the candidate has qualified examination for proficiency in English or not. In case, the candidate's proficiency in English is not found satisfactory, the candidate is required to do a course in communication skills.

ELIGIBILITY FOR REGISTRATION AS SCHOLAR FOR THE DEGREE

8. A student shall be formally registered as a Scholar for the Ph.D. Degree after he has complied with the following:

(a) Has completed his course work with a minimum CGPA of 6 or 55% marks.

(b) Has submitted a research plan duly recommended by RAC, and approved by VC; and

PERFORMANCE MONITORING

9.1. The academic/research progress of each student/Scholar will be monitored by RAC. For this purpose, each scholar will be asked to submit a progress report/synopsis at the end of each Semester to his supervisor(s). On receipt of the progress report, the supervisor(s) shall arrange with RAC for a review.

9.2. The supervisor(s)/RAC will evaluate the progress report of the student through a seminar at the end of each semester

9.3. 'Satisfactory'/unsatisfactory (US) grades are to be awarded during that Semester, along-with recommendation to continue registration in next Term. The scholar needs to be informed in each case with suitable advisories.

9.4. For the first appearance of 'US' grade, a warning would be issued to the scholar in writing.

9.5. If there are two consecutive 'US' reports, the registration will stand terminated.

9.6. Submission of progress report and semester seminars should continue till submission of thesis.

9.7. The academic calendar will include the dates for the submission of progress reports.

MINIMUM / MAXIMUM REGISTRATION DURATION REQUIREMENT

10. (a) Scholar shall be required to be registered for the degree for a period of not less than three calendar years (36 months) from the date of his initial registration. The period may be reduced in case of exceptional performance by the scholar after approval from the Vice Chancellor.

(c) The scholars of all categories shall normally submit their thesis within a period of six years from the date of their initial registration. However, as a special case, this limit may be extended to a maximum of seven years on the recommendation of RAC and approved by the Vice-Chancellor after which the registration shall stand cancelled automatically.

(d) Ph.D. students who have been registered for five or more years in the Ph.D. program are required to submit an application on the approval form, for extension of Ph.D. registration to the subsequent year in the Ph.D. program. This application must be completed and submitted on or before the last date for completing the progress seminar prior to the year for which extension of Ph.D. registration is required.

PLACE OF WORK, PROGRESS AND DURATION

11. On the recommendation of the DRC and the Head Research, the University may allow the research work for the Ph.D. degree to be partially or wholly carried out at another organization with the following provisions:

    (a) The external organization where a scholar wishes to carry out the research work partially or wholly shall have to be recognized by the University before such work is undertaken.

    (b) An external organization may be granted recognition by the University as an approved place of work.

        (i) The recognition shall normally be given only for the purpose of the individual research project for a particular student/scholar.

        (ii) The details of research facilities available at the organization shall be furnished by the student/scholar along with the application for admission to Ph.D. program.

        (iii) The Head Research shall examine the details given and may decide either to ask for further information, or even collect first-hand information, if necessary, by deputing faculty member(s) to visit the organization. Only when the Head Research is fully convinced about the adequacy of the research facilities and the credentials of the external supervisor, it shall recommend the case to the Vice Chancellor.

SYNOPSIS

12.1. Prior to the submission of the synopsis and thesis, the following requirements have to be met by the student:

    (a) completed the course work requirement successfully,

    (b) completed the research Work,

    (c) A Ph.D. Scholar must publish at least one Research Paper in refereed Journal and make two Paper Presentations in Conference/Seminar before the submission of the dissertation/thesis for adjudication and produce evidence for the same in the form of presentation certificate and/or reprints.

12.2. Holding of Pre-Ph.D. seminar by RAC is an essential requirement before it considers the synopsis of a Ph.D. scholar. On completion of the research work, the scholar shall submit to RAC, 5 copies of the synopsis including bibliography of research work. The RAC will forward the synopsis with its recommendations to Head Research.

12.3. The scholar shall be required to submit fresh synopsis if he fails to submit his thesis within 3 months of the submission of the earlier synopsis.

12.4. However, in case a scholar fails to submit his thesis within the stipulated time and has suitable justification for the same, then the following procedure is to be followed;

(a) The PhD Scholar may apply to the Head Research through the Supervisor(s) and the RAC for grant of some more specific time for submission of the PhD Thesis.

(b) The Supervisor(s)/ RAC may forward the application to the Head Research either supporting the extension or rejecting it, with full justification in either case.

(d) After giving full consideration and examining the progress of the PhD scholar from the date of registration, the Head Research would give recommendation to the Vice Chancellor for final decision and approval. In any case, the extension for submission of the PhD Thesis cannot be more than two months from the earlier given date for submission.

(e) The Vice Chancellor will give his final decision and approval.

12.5. In case, a PhD scholar fails to submit the PhD thesis even within the granted extended period, his PhD synopsis and the seminar shall be treated as cancelled. He has to start the process of submitting fresh PhD synopsis and giving a fresh PhD synopsis seminar following the normal procedure. No second extension will be granted.

BOARD OF EXAMINERS

13.1. Nomination: On receipt of the title and synopsis of the thesis, the Head Research will appoint a Board of Examiners for each scholar.

(a) Two panels of examiners each consisting of five experts having long experience and good standing in the relevant field of the PhD work, will be proposed by the RAC to the Head Research who on accepting the same shall get it approved by the Vice-Chancellor. A person working in the same laboratory (ies)/Institution(s) where Research Scholar is employed cannot, however, be appointed as external examiner for evaluating the Thesis of that Research Scholar. Further no person can be appointed as External Examiner from Laboratory/Institution to which the Joint supervisor(s) of the Research Scholar belongs. The supervisors while compiling the panel should consider the names of the examiners whose research work is referred in the Theses or who work in the same field/area.

(b) **The first panel will have experts from within Uttar Pradesh geographically spread over the entire state and the second panel will have experts from outside Uttar Pradesh.**

(c) The Vice-Chancellor will finalize the examiners. The Vice- Chancellor, if deemed necessary may also nominate one examiner from foreign or outside the panel.

(d) The approved Examiners will be approached, along with copy of the synopsis seeking their consent.

(e) The supervisor(s) shall be the internal examiner(s) and will be required to give an evaluation report on the thesis on the prescribed.

(f) The Head Research shall take appropriate steps to receive the reports from the examiners of Ph.D. thesis within a period of six months from the date of submission of the thesis.

THESIS SUBMISSION

14.1. The thesis shall be written in English in the specific format and shall contain a critical account of the scholar's research. It should be characterized by discovery of facts or fresh approach towards interpretation of facts and theories or significant contribution to knowledge of development or a combination of these. It should bear evidence of the scholar's capacity for analysis and judgment as well as his ability to carry out independent investigation, design or development. A thesis may be supplemented by published work, if necessary. No part of the thesis or supplementary published work shall have been submitted for the award of any other degree. An undertaking/ certificate to the above effect attesting to the originality of the work, vouching that there is no plagiarism and the work has not been submitted for award of any other degree/diploma to any other Institute shall be provided by the scholar and supervisor.

14.2. A scholar may submit his thesis within the time period as stipulated in rules provided that:

(a) He has completed the minimum period of registration as provided in rule 10.

(b) He has become a scholar for the award of Ph.D. degree as provided in rule 8.2 and

(c) He has submitted the title and synopsis of the thesis at least one months prior to the submission of the thesis.

14.3. The scholar shall initially submit three copies of the thesis with a soft cover. In case of co supervision four/five copies of thesis shall be submitted by the scholar.

14.4. The Thesis shall be put through anti plagiarism software to detect any kind of Academic dishonesty. A certificate in this reference is to be issued by Departmental Academic Integrity Panel (DAIP).

THESIS EVALUATION

15.1. Each examiner will be requested to submit to the Head Research a detailed assessment report and his recommendations, on the prescribed Performa, within six weeks of the date of receiving the thesis. The views of examiners must specifically be sought on that the theses is a piece of research work characterized by:

(a) The discovery of facts, or

(b) A fresh approach towards interpretation and application of facts or theories, or a distinct advance in technology.

(c) On the scholar’s capacity for critical examination and sound judgment.

(d) Whether or not major findings of the Thesis have already been published in referred Journals/Conferences or worthy of such publications. In case revision of Thesis is recommended, suggestions for the improvement may also be given.

(e) Quality of research work with respect to international standards of doctoral thesis.

15.2. In the event that the thesis report is not received from an examiner within a period of three months, the Head Research may appoint another examiner in his place for evaluating the thesis from the panel.

15.3. In the event of disagreement between the external examiners, the Head Research may as a special case, appoint another external examiner, if the merit of the case so demands. This examiner will report independently to the Head Research.

15.4. Re-Registration in case of rejection of thesis/requiring major revision:

(a) The candidate may, however, be allowed to renew his/her registration to continue the Ph.D. work on the same topic and under the same supervisor(s) for another minimum period of one year. A fresh Thesis has to be submitted by the candidate within two years but not earlier than one year of renewal. The normal process of the evaluation will be followed afresh.

(b) If a Ph.D. scholar, who has been allowed to renew registration to continue for PhD degree after his/her thesis was rejected/required major revision , fails to submit the fresh thesis within two Years as specified above, his/her PhD renewal of registration will be totally terminated once for all.

(c) The registration of a PhD scholar expires:

(i) On completion of the allowed maximum period of registration even after granted extension, or

(ii) On the final rejection of the thesis, even after submission/re-submission of the PhD thesis.

(d) No second renewal of registration is permitted.

VIVA-VOCE (OPEN DEFENCE)

16.1. A scholar who has been recommended for viva-voce examination on the basis of thesis evaluation shall be required to defend his work/thesis orally before a duly constituted committee hereinafter referred to as Oral Defense Committee (ODC) during working hours of the University. The presentation shall be well publicized and open to all members of the University

16.2. The Recommendations and the evaluation reports from all the examiners including the supervisor(s) will be placed before the Vice-Chancellor for further action

16.3. If the Vice-Chancellor finds the recommendations and the evaluation Reports from all the examiners (i.e. including internal examiners) satisfactory, the date of final Viva-Voce

examination will be decided in consultation with the External Indian Viva-Voce Examiner.

16.4. The ODC, shall be appointed by the Vice Chancellor and it shall consist of

(a) A professor of the University, outside the department as Chairman;

(b) The research supervisor(s);

(c) A faculty member of the University conversant with the subject to act as an internal examiner; and

(d) The Indian External Examiner.

16.5. The Indian External Examiner will invariably be part of the board of examiner for the Viva-Voce Examination (Open Defense). In other words, it is not permissible to substitute the external examiner in the Ph.D. Viva Voce examination by an examiner from within the University. However, the external examiner could participate in the examination by means of Video Conferencing in case he could not be physically present for whatever reason(s). The Chairperson of the ODC would be required to certify the acceptance of the Thesis and successful conduct of the Ph.D. Viva Voce Examination on behalf of the external examiner, when the external examiner participated through Video Conferencing.

16.6. On the completion of all stages of examination, the Oral Defense Committee shall recommend to the Head Research, one of the following courses of action:

(a) That the degree be awarded;

(b) That the scholar be re-examined at a later specified time in a specified manner;
(c) That the degree shall not be awarded;

In case of (a) and (b), the Oral Defense Committee (ODC) shall also provide to the scholar a list of all corrections and modifications in the thesis (if required) including suggestions made by the examiners during the thesis evaluation.

16.7. The candidate will be required to submit the final version of the thesis in the required format, incorporating all the suggestions of the Viva-Voce Board, both in hard as well as soft forms within the time limit specified by Head Research. The incorporation of the required changes will be certified by supervisor(s) and verified by Head Research.

AWARD OF Ph.D. DEGREE

17.1. On receipt of the final version of thesis, Registrar will present the same along with reports of all examiners to the Vice Chancellor who shall finally decide on award of Ph.D. degree to the candidate or otherwise.

17.2. The Degree shall be awarded by the Academic Council provided that:

(a) The Oral Defense Committee so recommends;
(b) The scholar produces a 'No Dues Certificate' in the prescribed form, and

(c) The scholar has submitted three hard cover copies of the thesis; one for the Department's/Centre's Library and one for the Central Library and one for INFLIBNET. Thesis should incorporate all necessary/ corrections/ modifications pointed out by the examiners or ODC and duly certified by the supervisor.

(e) The hard bound copies of the Ph.D. thesis, submitted after the viva-voce examination, must contain the following copyright certificate in the beginning of the thesis, on a separate page on the left side:

(f) IIMT UNIVERSITY, MEERUT, ALL RIGHTS RESERVED

(i) A Provisional Certificate would be issued to the candidate, if applicable.

(ii) The final degree will be awarded in the Convocation.

LEAVE

19.1. A student/scholar will be entitled to avail leave as per Leave Rules/Attendance Rules formulated and amended from time to time by the Academic Council.

19.2. (a) Research Scholar is required to carry out his research work regularly under the guidance of the Supervisor(s), without any interruption during the period he enjoys the assistantship.

(b) During Course work: A full-time Ph.D. student, during his stay at the University will be entitled to leave for 30 days (Non accumulative 15 days per semester) including leave on medical grounds, per academic year. He will not be entitled to mid-Term breaks, summer and winter vacation at the end of the Term till completion of course works.

(c) Leave beyond 30 days in an academic year may be granted to a Research Scholar in exceptional cases, by the Head of the Department/ Centre concerned, subject to the following conditions:

(i) The leave beyond 30 days will be without Assistantship/Scholarship; and

(ii) Such an extension of up-to additional 30 days will be granted only once during the program of the Scholar.

(iii) The leave may be subject to the approval of the Head of Department/Centre concerned on the recommendation of the Supervisor; and a proper leave account of each scholar shall be maintained by the Department/ Centre.

(d) After Completing the Course Work

A full-time Ph.D. scholar during his stay at the University will be entitled to leave for 30 days per academic year (Non accumulative 15 days per semester). He will not be entitled to mid-Term breaks, summer and winter vacations. In addition, a Ph.D. scholar who has completed his course work may be granted leave on medical grounds up to 10 days per academic year.

(e) The women research scholars will be eligible for Maternity Leave as per University leave rules/rules of the organization awarding assistant ship.

(f) Special Leave may be granted to attend Seminars/Conferences in India/abroad to present research papers, with the permission of the Dean/School/College is admissible.

ATTENDANCE

20. A Ph.D. student irrespective of the source of research assistantship including self-financing student not drawing any assistantship and sponsored student, while pursuing course work, must attend at least 75% of classes in each course in which He is registered.

In case his attendance falls below 75% in any course during a month. Further, if his attendance again falls short of 75% in any course in any subsequent month in that Term his studentship will be terminated. A research scholar after having completed the course work must attend to his research work on all the working days and mark attendance except when He is on duly sanctioned leave. The requirement of 75% attendance will apply as above on daily attendance except in the cases where longer leave has been duly sanctioned within the leave entitlement of the student. For the above purpose, if 75% works out to be a number which is not a whole number, the immediate lower whole number will be treated as the required 75% attendance.

WITHDRAWAL FROM SEMESTER / COURSES

21.1. A student/scholar may be permitted to withdraw by the Head Research from all the courses registered by him or the entire Term, on medical grounds supported by a medical certificate from the University Medical Officer. The medical certificate issued by a registered Medical Practitioner will also be acceptable in those cases where the scholar has valid reasons for his absence from the University. Withdrawal may also be granted by the Head Research provided he is convinced that the scholar cannot pursue his studies for the reasons beyond his control.

21.2. Under no circumstances will a request for withdrawal be entertained after the end term tests have begun. Student/Scholar should present the medical certificate in support of his absence on health reasons within two days of his re-joining the University, if not produced already. Withdrawal will not be granted retrospectively.

21.3. The period of authorized absence in the Term should not be less than eight weeks of contact period for Term withdrawal to be granted. Regularly in attending the classes and satisfactory performance in the minor(s) if any, held prior to the date of application for withdrawal are the factors which would be taken into account while recommending/granting withdrawal.

21.4. Any Semester withdrawal will count towards the maximum limit of six years as stipulated.

CANCELLATION OF REGISTRATION

22. Registration of a student/scholar shall be cancelled in any one of the following eventualities, after due approval of Vice Chancellor.

(a) If he absents himself for a continuous period of four weeks without prior intimation/ sanction of leave.

(b) If he resigns from the Ph.D. Program and the resignation is duly recommended by the DRC.

(c) If he fails to renew his registration in any Term subject to the provisions contained in these Ordinances & Regulations.

(d) If his academic progress is found unsatisfactory in terms of rule.9.6.

(e) If his CGPA is below 7.00 or less than 55% at any time while doing course work and continues to be so after allowing additional chance as per rules.

(f) If he is found involved in an act of misconduct and/or indiscipline and termination is recommended by a competent authority.

RULES REGARDING CONDUCT AND DISCIPLINE

23. Following rules shall be applicable to all students and research scholars in the matters of conduct and discipline:

(a) Student/ Scholars shall show due respect to the teachers of the University, and to the employees of the University

(b) Research Scholars are required to develop a friendly camaraderie with fellow students. In particular, they are expected to show kindness and consideration to the new students admitted to the University every year.

(c) Ragging in any form is banned by law: acts of ragging will be considered as gross indiscipline and will be severely dealt with.

(d) The following acts of omission and/or commission shall constitute gross violation of the code of conduct and are liable to invoke disciplinary measures:

(i) Ragging;

(ii) Lack of courtesy and decorum; indecent behavior anywhere within or outside the campus;

(iii) Willful damage or stealthy removal of any property/belongings of the University/ Hall or of fellow students;

(iv) Possession, consumption or disruption of alcoholic drinks or any kind of hallucinogenic drug;

(v) Adoption of unfair means in the examinations;

(vi) Mutilation or unauthorized possession of library books;

(vii) Noisy and unseemly behavior, disturbing studies of fellow students.

(e) Commensurate with the gravity of the offence, the punishment may be reprimand, fine, expulsion from the hostel, debarment from an examination, rustication for a specified period or even outright expulsion from the University.

DEPOSITORY WITH UGC

24. Following the successful completion of evaluation process and the announcement of the award of the PhD degree, a soft copy of the PhD thesis will be sent to the UGC (INFLIBNET) within a period of thirty days.

MISCELLANEOUS

25.1. In case a scholar is found adopting of suspected of adopting unfair means before, during and after the examination or lifting of some other's work(s) and inserting it in his/her project, seminar and dissertation etc. without proper acknowledgement, credit and reference or plagiarizing the dissertation/project report etc., such penal action shall be taken by the University as may be necessary to up hold the sanctity and integrity of the examination system and the creditability of the University.

25.2. Any patent, design knowhow/copyright etc. emerging from the thesis work will be filed and owned by the IIMT University. All those who contributed in the invention will be the "Inventors".

25.3. Notwithstanding anything contained in these Ordinances & Regulations, all the PhD scholars will be governed by the rules and procedures framed by the University in this behalf, and on matters of general discipline and in force from time to time. The decision of the Vice Chancellor in all matters related to Ph.D. shall be final and binding on all parties.

INTERPRETATION

26. Any doubt or dispute arising about the interpretation of these Ordinances and Regulations shall be referred to the Chairman, Academic Council whose decisions shall be final.

Syllabus for Ph.D. Course Work
(Effective from the Session: 2020-21)

The PhD course for the Research Scholars would consist of five papers. Out of these three papers would be compulsory, one optional (to be chosen from five given as under) and one Oral/Seminar-

S. No	Subject Code	Subjects	Category	periods			Marks					Credits
							Internal			External	Total	
				L	T	P	CT	TA	Total			
1	PHD-101	Research Methodology	CORE	4	0	0	20	10	30	70	100	4
2	**PHD-102**	**Discipline specific**										
3	PHD-102 A	Pharmaceutics	CORE	4	0	0	20	10	30	70	100	4
4	PHD-103	Quantitative Analysis	CORE	2	0	0	10	5	15	35	50	2
5	CPE-RPE	Research and Publication ethics	CORE	2	0	0	10	5	15	35	50	2
	PHD-SP	Seminar/ Oral	DSE	2	0	0	0	0	50	0	50	2

Discipline Specific Elective Courses (Any one)

	Subject Code	Subjects	Category	Periods			Marks					Credits
							Internal			External	Total	
				L	T	P	CT	TA	Total			
1	PHD-102 B	Pharmaceutical Chemistry	Elective	4	0	0	20	10	30	70	100	4
2	PHD-102 C	Pharmacology	Elective	4	0	0	20	10	30	70	100	4
3	PHD-102 D	Pharmacognosy	Elective	4	0	0	20	10	30	70	100	4

RESEARCH METHODOLOGY AND BIOSTATISITCS				
Course Code PHD - 101	**Theory Course**	**L-P-C**	**4-0-4**	
Course Contents				**HOURS**
Unit I	**Introduction:** Statistics, Biostatistics, Frequency distribution **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems **Correlation**: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples **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 **Parametric test**: t-test(Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference.				**8**
Unit II	**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				**8**
Unit III	**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression models				**8**
Unit IV	**Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism **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.				**8**
Unit V	**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 **A) Design and Analysis of experiments:** **Factorial Design:** Definition, 22, 23design. Advantage of factorial design **B) Response Surface methodology**: Central composite design, Historical design, Optimization Techniques **C) Akaike's Information criterion:** Definition, calculation and statistical data				**8**
Books Recommended	1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, 2. Publisher Marcel Dekker Inc. New York. 3. Fundamental of Statistics – Himalaya Publishing House- S.C. Gupta 4. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam, 5. Design and Analysis of Experiments – Wiley Students Edition, 6. Douglas and C. Montgomery				

Discipline Specific (Pharmaceutics)			
Course Code PHD–102A	**Theory Course**	**L-P-C**	**4-0-4**

	Course Contents	HOURS
Unit I	**A) Pre formulation Studies:** (i) Physiochemical aspects: pKa, Partition coefficient, Reaction kinetics & Mechanism. (ii) Biological aspects: Reaction Kinetics & Mechanism **B) Drug solubility studies** (i) General principle definition, the phase rule solubility expression, determination of solubility, (ii) Solvent solute interaction polar solvent non-polar solvent and semi-polar solvent, Solubility calculations (ii) Types of solution, the solubility of gases in liquids, effect of pressure, temperature, salt and chemical reactions.	**8**
Unit II	**A) Concepts and system design for rate controlled delivery:-** Rate programmed, Activation Modulated & feedback regulated drug delivery system, effect of system parameters on controlled release drug delivery. **B) Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/disadvantages, factors influencing, physicochemical & biological approaches and mechanism of drug delivery from SR/CR formulation.	**8**
Unit III	**Topical Drug Delivery Systems:** Factors affecting percutaneous absorption of drugs, sorption promoters, absorption enhancement by energy input - iontophoresis, sonophoresis and electroporation, pharmacokinetics of skin permeation, Design, formulation, development, characterization, advantages and limitation of hydrogel, organogel, insitugel, gel using thixotropic behavior. **Targeted drug delivery system**: Different levels of targeting-first order, second order and third order targeting, active and passive targeting, EPR effect, receptor mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting, active and passive targeting, Monoclonal antibodies, Carrier systems-Microspheres, nanoparticles, liposomes, Released erythrocytes etc.	**8**
Unit IV	**Parentral drug delivery system:** Major routes of parentral administration, selection, design & development. Biopharmaceutics of sustained/controlled release pattern of drug products, polymer microspheres and their biocompatibility and dispersed DDS.	**8**
Unit V	**A) Regulatory Considerations**: Bioavailability enhancement methods. Introduction to i*n-vivo in-vitro* correlation and its significance. Review of regulatory requirements for conduction of BE studies. Design of single dose bioequivalence study. **B) Biopharmaceutical & Pharmacokinetic aspects of CRDDS**: Strategies and design, diffusion and dissolution controlled release, ion-exchange resins, pH-independent formulations, osmotically controlled release, Pharmacokinetics of drugs following zero/one/ two compartment open models with first order elimination kinetics.Absorption rate constant determination using Wagner-Nelson and Loo-Reigelman method. **C) Release mechanism and interpretation of Kinetic data.**	**8**

Books Recommended	1. Notari, R.E, Biopharmaceutics and Pharmacokinetics-An introduction, Marcel Dekker Inc. New York 2. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publishing A.G. Basel, Switzerland. 3. Gibaldi, M., Biopharmaceutics & Clinical Pharmacokinetics, Pharma Book Syndicate, Hyderabad. 4. Robert, Rodriguezdiaz, Analytical Techniques for Biopharmaceuticals Development. 5. Curry, S. H., Drug Disposition & Pharmacokinetics, Pharma Book Syndicate, Hyderabad. 2017. 6. Bentley S Textbook of Pharmaceuticals, 8Th Edition by E. A. Rawlins, Elsevier India, 2010. 7. Rawlins E A, Bentley's Textbook of pharmaceutics, Elsevier 8th edition 2015. 8. Carstensen J T, Rhodes C T, Drug Stability: Principles And Practices, 3rd Revised Edition 2000. 9. Bankar u v, pharmaceutical dissolution testing vol. 49 edition 1991, Taylor & Francis India Pvt Ltd 10. Raymond R C, Handbook of Pharmaceutical Excipients 6th Revised Edition 2009 11. Bauer E.J, Pharmaceutical Packaging Handbook, informa healthcare 2009 12. Naizi S K, Handbook of preformulation chemical, biological & botanical drugs, CRC press 2006. 13. Rath bone MJ, Hadgrapt J, modified release drug delivery technology, 2nd edition informa healthcare

Discipline Specific (Pharmaceutical Chemistry)				
Course Code PHD-102(B)	**Theory course**	**L-P-C**	**4-0-4**	
Course Contents				**HOURS**
Unit I	Study of Basic chemistry including E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations. E1 verses E2 reactions, Factors affecting E1 and E2 reactions. 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.			**8**
Unit II	Various named reaction with their mechanism and their applications: Nucleophilic addition, electrophilic substitution, Nucleoplhilic substitution, electrophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, Hoffmann bromamide degradation reaction.			**8**
Unit III	Study of following class of drugs classification, mechanism of action and their synthetic approach of new generation molecules of following class of drugs: 1. Antiviral agents: Zidovudine, Amantadine 2. Tetracycline: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline. 3. Aminoglycosides: Streptomycin, Neomycin, Kanamycin. **Combinatorial Chemistry**: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.			**8**
Unit IV	**Chemotherapy of microbial infections:** **1. Antibiotics:** Penicillins, cephalosporins, β- Lactamase inhibitors, Monobactams. **2. Antifungals**: Ketoconazole and clotrimazole **3. Antiseptics and disinfectants:** Benzalkoniumsulfonide			**8**
Unit V	Study of following class of drugs classification, mechanism of action and their synthetic approach of: a) **Macrolide:** Erythromycin Clarithromycin, Azithromycin. Miscellaneous: Chloramphenicol*, Clindamycin. b) **Quinolines**: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, c) **Antineoplastic agents**: Chlorambucil, Methotrexate, Vincristine QSAR Studies: Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.			**8**
References	1) Medicinal Chemistry by Burger, Vol I –VI. 2) Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincottilliams& Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi. 3) Comprehensive Medicinal Chemistry – Corwin and Hansch. 4) Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore 5) Introduction to Quantitative Drug Design by Y.C. Martin.			

	6) Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi. 7) Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.. 8) Principles of Drug Design by Smith. 9) The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.

Discipline Specific (Pharmacology)			
Course Code PHD-102(C)	**Theory course**	**L-P-C**	**4-0-4**

Course Contents		**HOURS**
Unit I	**General Pharmacology** Combined Drug Administration : Indifference, Synergism, Antagonism & Adverse Drug Reactions, Factors Modifying Drug Action Introduction : Pharmacology : A Foundation to Clinical Practice Pharmacodynamics: Principles of Drug Action, Mechanism of Drug Action, Receptors; Pharmacokinetics: Absorption, Distribution, Biotransformation, Elimination & New Drug Development **Autonomic Pharmacology and P.N.S.** Adrenergic Drugs; Parasympatholytic drugs; Antiadrenergic drugs Parasympathomimetic drugs; General Considerations and Neurohumoral Transmission	**8**
Unit II	**Cardiovascular and Nephropharmacology** Antihypertensives and Pharmacotherapy of Hypertension; Antianginal Drugs and Pharmacotherapy of Angina Pectoris; Management of Congestive Cardiac Failure; Diuretics* and Antidiuretics; Pharmacotherapy of Shock & Vassopressor agents **Haematological Pharmacology** Haematinics; Anticogulants, Thrombolytic, Antiplatelets and Coagulants; Haematopoietic Factors **Endocrine Pharmacology** Corticosteroids; Thyroxin and Antithyroid Drugs; Pharmacotherapy of Diabetes Mellitus; Hormonal Contraceptives; Paratharmone and Drugs affecting Calcium Metabolism; Estrogen, Progestins and their Antagonists; Testosterone and Anabolic Steroids	**8**
Unit III	**Chemotherapy** Sulfonamides, Cotrimoxozole, Quionolones; Beta-Lactam Antibiotics; Aminoglycosides; Broad Spectrum Antibiotics; General Considerations; Macrolides; Principles of Cancer Chemotherapy Chemotherapy of Tuberculosis, Leprosy, Malaria, Viral Infection, U.T.I, Amoebiasis, S.T.Is	**8**
Unit IV	**Neuropsychiatric and Perioperative Pharmacology** Analgesics: Opioids and N.S.A.I.Ds; Hypnosedatives; Local Anaesthetics; Preanaesthetic Medication; Pharmacotherapy of Epilepsy; Antiparkinsonian Drugs; General Anaesthetics; Psychopharmacology **Gastrointestinal Pharmacology** Pharmacotherapy of Acid Peptic Disease; Antidiarrhoeals and Management of Diarrhoea; Antiemetics and Management of Vomiting; Purgatives and Management of Constipation; Emetics	**8**
Unit V	Detailed Study of guidelines of CPCSEA, ICH, OECD, GLP, ICMR.	**8**

	Alternative to animal experimentation viz. cell lines, radiolig and binding assay, patch clamp and ELISA, stem cell research Gene Therapy Immunobiological assays	
References	1. Text of book of pharmacology by PadmajaUdaykumar. 2. Priniciples of Pharmacology by H.L.Sharma , K.K.Sharma. 3. Screening methods in Pharmacology by Robert Turner.A. 4. Drug discovery & evaluation by Vogel H.G. 5. Fundamental of experimental Pharmacology by M.N.Ghosh. 6. Hand book of experimental Pharmacology by S.K.Kulkarni.	

Discipline Specific (Pharmacognosy)				
Course Code PHD-102(D)	**Theory course**	**L-P-C**	**4-0-4**	
Course Contents				**HOURS**
Unit I	Recent development in the research on natural medicinal products introduction biological and pharmacological activities isolation and characterization studies of different class of phytoconstituents alkaloids, glycoside, steroids, saponins etc.			**8**
Unit II	Natural product drug Discovery from different sources (Marine, microbial, mineral etc:- Introduction, recent development methods of extraction and isolation, applications etc. Overview of novel herbal formulations: phytosome, liposome, microspheres, novel vascular herbal formulation etc.			**8**
Unit III	Standardization of herbal drug formulations, conventional methods, modern techniques, (role of genetic markers are RAPD, DNA, fingerprinting technique etc) WHO guidelines for assessment of crude drugs, evaluation of Identity, purity and quality of crude drugs, determination of pesticide Residue, determination of microorganisms, determination of arsenic and other heavy metals			**8**
Unit IV	Herbal drug regulatory affairs role and importance of national and international regulatory bodies in assessment of quality of herbal drugs and formulations, OECD guidelines and ICH guidelines			**8**
Unit V	In vitro and In vivo screening methods for diabetes, hepato-protective, analgesic, nootropic, antimicrobial and antioxidant activities. Alternative to animal experimentation viz. cell lines, radio-ligand binding assay			**8**
References	1. Pharmacognosy by C K Kokate, A P Purohit& S B Gokhale 2. Herbal Drug Technology by S S Agrawal & M Paridhavi 3. Quality Control of Herbal Drugs by Pulok K Mukherjee 4. Experimental Phytopharmacognosy: A comprehensive guide by S S Khadabadi, S L Deore & B A Baviskar. 5. Text book of Pharmacognosy by Trease& Evan's. 6. Hand book of experimental Pharmacology by S.K.Kulkarni. 7. Drug discovery & evaluation by Vogel H.G.			

Quantitative Analysis:				
Course code PHD-103	**Theory course**	**L-P-C**	**4-0-4**	
Course Contents				**HOURS**
Unit I	**a) UV-Visible spectroscopy**: Introduction, Beer's Lambert's Laws, Instrumentation associated with UV-Visible spectroscopy, maxima wavelength calculation of different compounds and Applications of UV-Visible spectroscopy. **b) FTIR**: Introduction, Theory, Instrumentation and applications, **c) Elemental analysis and related contents**: Qualitative and Quantitative analysis of elements.			**8**
Unit II	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, **Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI,			**8**
Unit III	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: **a)** HPTLC **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** LCMS and GCMS			**8**
Unit IV	**Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **a)** Paper electrophoresis **b)** Gel electrophoresis **c)** Capillary electrophoresis **d)** Zone electrophoresis **e)** Moving boundary electrophoresis			**8**
Unit V	a) **DSC and DTA**: Introduction, theory, principle, Instrumentation and applications in pharmaceutical analysis. b) **TGA**: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.			**8**
References	**1)** Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004. **2)** Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998. **3)** Instrumental methods of analysis – Willards, 7th edition, CBS publishers. **4)** Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997. **5)** Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991. **6)** Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.			

	7) Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series **8)** Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi. Text book of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Research and Publication Ethics				
Course code PHD-104	**Theory course**	**L-P-C**	**4-0-4**	
Course Contents				**HOURS**
Unit I	**PHILOSOPHY AND ETHICS** 1. Introduction to philosophy: definition, nature and scope, concept, branches 2. Ethics: definition, moral philosophy, nature of moral judgments and reactions **DATABASES AND RESEARCH METRICS** **A)** Databases 1. Indexing databases 2. Citation databases: Web of Science, Scopus, etc. **B)** Research Metrics 1. Impact Factor of journal as per Journal Citation Report, SNIP, SIR, IPP, Cite Score 2. Metrics: h-index, g index, i10 index, altmetrics			**8**
Unit II	**SCIENTIFICCONDUCT** 1. Ethics with respect to science and research 2. Intellectual honesty and research integrity 3. Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP) 4. Redundant publications: duplicate and overlapping publications, salami slicing 5. Selective reporting and misrepresentation of data			**8**
Unit III	**PUBLICATION ETHICS** 1. Publication ethics: definition, introduction and importance 2. Best practices / standards setting initiatives and guidelines: COPE, WAME, etc. 3. Conflicts of interest 4. Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types 5. Violation of publication ethics, authorship and contributor ship 6. Identification of publication misconduct, complaints and appeals 7. Predatory publishers and journals			**8**
Unit IV	**OPEN ACCESS PUBLISHING** 1. Open access publications and initiatives 2. SHERPA/RoMEO online resource to check publisher copyright & self-archiving policies 3. Software tool to identify predatory publications developed by SPPU 4. Journal finder/journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggested, etc.			**8**
Unit V	**PUBLICATION MISCONDUCT** **A)** Group Discussions 1. Subject specific ethical issues, FFP, authorship 2. Conflicts of interest 3. Complaints and appeals: examples and fraud from India and abroad **B)** Software tools: Use of plagiarism software like Tumitin, Urkund and other open source software tools			**8**