

आईएफटीएम विश्वविद्यालय, मुरादाबाद, उत्तर प्रदेश

IFTM University, Moradabad, Uttar Pradesh NAAC ACCREDITED

SCHOOL OF PHARMACEUTICAL SCIENCES, PHARMACY ACADEMY AND SAHU ONKAR SARAN SCHOOL OF PHARMACY

(FACULTY OF PHARMACY)

IFTM UNIVERSITY,

MORADABAD.

www.iftmuniversity.ac.in

Study & Evaluation Scheme of Diploma in Pharmacy

Programme

Diploma in Pharmacy

Course Level

Diploma

Duration

Two academic Year (Full Time)

Medium of instruction

Hindi, English

Minimum Required Attendance :

75%

Programme Outcomes (POs):

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

PO1: Have sound knowledge to assess various disease and pathological conditions.

PO2: Read, process and interpret the prescription.

PO3: Prepare, pack, label and dispense the prescribed medications in addition to non-sterile compounding.

PO4: Maintain of inventory record, analyze, organize and manage documents.

PO5: Solve problems as a part of healthcare system.

PO6: Demonstrate use of medical aids to patients.

PO7: Develop a positive aptitude for skill development and lifelong learning.

PO8: Provide empathy to chronic/emergency/economically back ward patients and their family.

PO9: Apply the ethics and code of conduct to patient's, healthcare providers, other pharmacy co-workers and as well as to the society.

PO10: Create awareness in society about the effective and safe use of medicines along with their storage conditions.

Faculty of Pharmacy IFTM University, Moradabad IFTM University

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Pharmacy Council of India New Delhi

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

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COMMITTEE MEMBERS

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

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1. Preamble

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

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

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

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

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

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

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

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

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

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

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

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2. Competencies for the Indian D.Pharm Holders

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

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

- 1. Review Prescriptions
- 2. Dispense Prescription / Non-Prescription Medicines
- 3. Provide Patient Counselling / Education
- 4. Hospital and Community Pharmacy Management
- 5. Expertise on Medications
- 6. Proficiency on drugs / pharmaceuticals
- 7. Entrepreneurship and Leadership
- 8. Deliver Primary and Preventive Healthcare
- 9. Professional, Ethical and Legal Practice
- 10. Continuing Professional Development
- 1. Review Prescriptions: The student should receive and handle prescriptions in a professional manner and be able to check for their completeness and correctness. Also, the prescribers should be contacted for any clarifications and corrections in the prescriptions with suggestions if any.
- **2. Dispense Prescription / Non-Prescription Medicines:** The student should be able to dispense the various scheduled drugs / medicines as per the implications of the Drug & Cosmetics Act and Rules thereunder. Also, the non-prescription medicines (over-the-counter drugs) should be dispensed 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.

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- **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.

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

Education Regulations 2020

Competencies	Pharmaceutics	Pharmaceutical Chemistry	Рһаrmаcognosy	& ymotsnA nsmuH Ygoloisyd9	Social Pharmacy	Рһагтасоюду	Community Pharmacy & Management	Biochemistry & Clinical Pathology	Pharmacotherapeutics	Hospital & Clinical Pharmacy	Pharmacy Law & Ethics	Practical Training
1. Review the Prescriptions	7	7	>	7		>	7	7	7	7	>	>
2. Dispense Prescription / Non-Prescription Medicines	>	7	>		>	7	7	>	7	7	7	>
3. Provide Patient Counselling / Education	7	7	>	7	>	7	7	7	>	7	7	>
4. Hospital and Community Pharmacy Management					>		7			7	7	>
5. Expertise on Medications	>	7	7	7	>	>	7	7	>	>	7	>
6. Proficiency on Pharmaceutical Formulations	>	>	7			>			>			>
7. Entrepreneurship and Leadership							7			7		>
8. Deliver Primary and Preventive Healthcare				7	>	>	7	7	>	7	>	>
9. Professional, Ethical and Legal Practice					>		7		7	7	7	>
10. Continuing Professional Development	>	>	7		>	>	7		7	7	7	>

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4. ER-2020 D.Pharm Syllabus - An Overview

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

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

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

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

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

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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.

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Practical Training: The goal of the practical training for the students is to provide a real-time, supervised experience on the professional tasks emphasised in their course of study. Further, it helps them to apply their acquired knowledge and skills in the professional working environment. The practical training intensively prepares the students with adequate competencies and qualifications required for the career opportunity in the future.

Thus, the ER 2020 D.Pharm syllabus is designed to nurture the students in all the three domains of Bloom's Taxonomy viz. cognitive (knowledge), affective (attitude) and psychomotor (skills). Further, it also provides ample of scope to the students for different learning styles viz. visual, auditory and kinaesthetic, i.e., 'see, hear and do'.

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

Criteria	Metrics
Number of subject areas (considering both theory & practical together)	11
Number of theory courses	11
Number of practical courses	10
Number of theory hours	825
Number of practical hours	600
Number of practical training hours	500
Number of tutorial hours	275
Number of course outcomes for theory courses	45
Number of course outcomes for practical courses	40
Number of courses which have given assignments	9
Number of assignment topics given	75
Number of assignments reports each student shall submit	27
Number of courses which have field visit	5
Number of field visit reports each student shall submit	9
Number of professional competencies	10

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5. Guidelines for the conduct of theory examinations

Sessional Examinations

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

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

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

Final Board / University Examinations

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

I. Long Answers (Answer 6 out of 7)	=		6	X	5 =	30	
II. Short Answers (Answer 10 out of 11)	=		10	χí	3 =	30	
III. Objective type Answers (Answer all 20)	=	20	Χ	1	=	20	
(Multiple Choice Questions / Fill-in the Blanks /							
One word OR one Sentence questions)							
Tatal	_		00	m	orle	_	

Total = 80 marks

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6. Guidelines for the conduct of practical examinations

Sessional Examinations

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

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

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

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

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

Total = 20 marks

Note:

- 1. For the courses having either assignments or field visit/s, the assessments of assignments or field visit/s shall be done directly for 10 marks and added to the sessional marks.
- 2. For the courses not having both assignment and field visit, the whole 20 marks shall be calculated from the sessional marks.

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^{*, \$} Only for the courses given with both assignments and field visit/s

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.

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7. ER-2020 D.Pharm Syllabus - Part I

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

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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 (COs): Upon successful completion of this course, the students will be able to

CO1: History of the profession of Pharmacy, Pharmacopoeia and Describe about the different dosage forms and their formulation aspects.

CO2: Explain the advantages, disadvantages, and quality control tests of different dosage forms.

CO3: Discuss the importance of quality assurance and good manufacturing practices.

CO4: Analyze the principles of pharmaceutical manufacturing, good manufacturing practices, and quality assurance.

CO5: Illustrate novel drug delivery systems and their applications in advanced pharmaceutical formulations.

Chapter	Topics	Hours	COs
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	CO1
2	Packaging materials: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	5	CO2
3	Pharmaceutical aids: Organoleptic (Colouring, flavouring, and sweetening) agents Preservatives: Definition, types with examples and uses	3	CO3
4	Unit operations: Definition, objectives/applications, principles, construction, and workings of: Size reduction: hammer mill and ball mill	9 2 An	CO4

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	Size separation: Classification of powders according to IP,		
3K	Cyclone separator, Sieves and standards of sieves		
	Mixing: Double cone blender, Turbine mixer, Triple roller	1	
	mill and Silverson mixer homogenizer		
	Filtration: Theory of filtration, membrane filter and sintered glass filter		
	Drying: working of fluidized bed dryer and process of freeze drying		
	Extraction: Definition, Classification, method,and applications		
5	Tablets - coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multilayered, etc.)	8	CO1
	Capsules - hard and soft gelatine capsules	4	
	Liquid oral preparations - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution	6	
	Topical preparations - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries	8	
	Nasal preparations, Ear preparations	2	
	Powders and granules - Insufflations, dusting powders, effervescent powders, and effervescent granules	3	
	Sterile formulations - Injectables, eye drops and eye ointments	6	
	Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.	4	
6	Basic structure, layout, sections, and activities of	5	CO3
	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		
7	Novel drug delivery systems: Introduction, Classification	5	CO5
	with examples, advantages, and challenges		

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PHARMACEUTICS - PRACTICAL

Course Code: ER20-11P

75 Hours (3 Hours/week)

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

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

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

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

- 1. Calculate the working formula from the given master formula
- 2. Formulate the dosage form and dispense in an appropriate container
- 3. Design the label with the necessary product and patient information
- 4. Perform the basic quality control tests for the common dosage forms

Practicals

- Handling and referring the official references: Pharmacopoeias, Formularies, etc. for retrieving formulas, procedures, etc.
- 2. Formulation of the following dosage forms as per monograph standards and dispensing with appropriate packaging and labelling
 - Liquid Oral: Simple syrup, Piperazine citrate elixir, Aqueous Iodine solution
 - Emulsion: Castor oil emulsion, Cod liver oil emulsion
 - Suspension: Calamine lotion, Magnesium hydroxide mixture
 - Ointment: Simple ointment base, Sulphur ointment
 - Cream: Cetrimide cream
 - Gel: Sodium alginate gel
 - Liniment: Turpentine liniment, White liniment BPC
 - Dry powder: Effervescent powder granules, Dusting powder
 - Sterile Injection: Normal Saline, Calcium gluconate Injection
 - Hard Gelatine Capsule: Tetracycline capsules
 - Tablet: Paracetamol tablets
- 3. Formulation of at least five commonly used cosmetic preparations e.g. cold cream, shampoo, lotion, toothpaste etc

4. Demonstration on various stages of tablet manufacturing processes

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- 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)

- Various systems of measures commonly used in prescribing, compounding and dispensing practices
- 2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, their generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical
- 3. Overview of various machines / equipments / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.
- 4. Overview of extemporaneous preparations at community / hospital pharmacy vs. manufacturing of dosage forms at industrial level
- 5. Basic pharmaceutical calculations: ratios, conversion to percentage fraction, alligation, proof spirit, isotonicity

Field Visit

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

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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 (COs): Upon successful completion of this course, the students will be able to

CO1: Describe the chemical class, structure and chemical name of the commonly used drugs and pharmaceuticals of both organic and inorganic nature.

CO2: Discuss the pharmacological uses, dosage regimen, stability issues and storage conditions of all such chemical substances commonly used as drugs.

CO3: Describe the quantitative and qualitative analysis, impurity testing of the chemical substances given in the official monographs.

CO4: Identify the dosage form & the brand names of the drugs and pharmaceuticals popular in the marketplace.

CO5: Discuss Antidotes and demonstrate understanding of their monographs. Explain preparation, usage, and storage conditions of official inorganic compounds.

Chapter	Topic	Hours	COs
1	Introduction to Pharmaceutical chemistry: Scope and objectives	8	CO1
	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.		
2	Volumetric analysis: Fundamentals of volumetric analysis,	8	CO2
	Acid-base titration, non-aqueous titration, precipitation		
	titration, complexometric titration, redox titration		
	Gravimetric analysis: Principle and method.		1
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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 permanganate Dental products: Calcium carbonate, Sodium fluoride, Denture cleaners, Denture adhesives, Mouth washes Medicinal gases: Carbon dioxide, nitrous oxide, 	7	CO3
4	Introduction to nomenclature of organic chemical systems with particular reference to heterocyclic compounds containing up to Three rings	2	CO4
	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, 	9	CO5
6	Duloxetine, Sertraline, Citalopram, Escitalopram, Fluvoxamine, Paroxetine Drugs Acting on Autonomic Nervous System	9	CO1

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	Dopamine*, Terbutaline, Salbutamol (Albuterol), Naphazoline*, Tetrahydrozoline. <i>Indirect Acting</i>		
	Agents: Hydroxy Amphetamine, Pseudoephedrine. Agents With Mixed Mechanism: Ephedrine, Metaraminol		
2	Adrenergic Antagonists: Alpha Adrenergic Blockers: Tolazoline, Phentolamine		
	 Phenoxybenzamine, Prazosin. Beta Adrenergic Blockers: Propranolol*, Atenolol*, Carvedilol 		
	 Cholinergic Drugs and Related Agents: DirectActing 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*		
7	Drugs Acting on Cardiovascular System	5	CO2
	 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 		
8	Diuretics: Acetazolamide, Frusemide*, Bumetanide, Chlorthalidone, Benzthiazide, Metolazone, Xipamide, Spironolactone	2	CO3
9	Hypoglycemic Agents: Insulin and Its Preparations, Metformin*, Glibenclamide*, Glimepiride, Pioglitazone, Repaglinide, Gliflozins, Gliptins	3	CO4
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	CO5
11	 Anti-Infective Agents Antifungal Agents: Amphotericin-B, Griseofulvin, Miconazole, Ketoconazole*, Itraconazole, 	8	CO1
	Fluconazole*, Naftifine Hydrochloride	mai	Not

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	 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, <i>Tetracyclines:</i> Doxycycline, Minocycline, <i>Macrolides:</i> Erythromycin, Azithromycin, <i>Miscellaneous:</i>	8	CO2
13	Chloramphenicol* Clindamycin		
13	Anti-Neoplastic Agents: Cyclophosphamide*, Busulfan, Mercaptopurine, Fluorouracil*, Methotrexate, Dactinomycin, Doxorubicin Hydrochloride, Vinblastine Sulphate, Cisplatin*, Dromostanolone Propionate	3	CO3

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PHARMACEUTICAL CHEMISTRY - PRACTICAL

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

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

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

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

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

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

Practicals

S. No.	Experiment		
1	Limit test for		
,	 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		

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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

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PHARMACOGNOSY - THEORY

Course Code: ER20-13T

75 Hours (3 Hours/week)

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

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

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

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

CO1: Identify the important and classification of common crude drugs of natural origin

CO2: Quality control of drugs of natural origin

CO3: Describe the crude drugs and fibers.

CO4: Discuss the principles of alternative system of medicines

CO5: Discuss economically important medicinal and aromatic plants. Describe nutraceuticals and cosmeceuticals

Chapter	Topic		Hours	COs
1	Definition, history, present status and scope of		2	CO1
	Pharmacognosy			
2	Classification of drugs:	8	4	CO1
	Alphabetical			
	 Taxonomical 			
	 Morphological 			
	 Pharmacological 			
	 Chemical 			
	Chemo-taxonomical	Cania	An	and
	(Pa)	2/1////////	Al /11	

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3		of adulteration of crude drugs	6	CO2
	Evaluation of cruc	le drugs		
4	identification tests, ther	ccurrence, distribution, isolation, apeutic activity and pharmaceutical terpenoids, glycosides, volatile oils,	6	СО
5	N-99	cal constituents and therapeutic categories of crude drugs.	30	CO
	Laxatives			
		Aloe, Castor oil, Ispaghula, Senna		
	Cardiotonic	Digitalis, Arjuna		
	Carminatives and G.I. regulators	Coriander, Fennel, Cardamom, Ginger, Clove, Black Pepper, Asafoetida, Nutmeg,		
	Astringents	Cinnamon Myrobalan, Black Catechu, Pale		
		Catechu		
	Drugs acting on	Hyoscyamus, Belladonna,		
	nervous system	Ephedra, Opium, Tea		
		leaves,Coffee seeds, Coca		
	Anti-hypertensive	Rauwolfia		
	Anti-tussive	Vasaka, Tolu Balsam		
8	Anti-rheumatics	Colchicum seed		
	Anti-tumour	Vinca, Podophyllum		
	Antidiabetics	Pterocarpus, Gymnema		
	Diuretics	Gokhru, Punarnava		
	Anti-dysenteric	Ipecacuanha		
3	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	Kaolin, Lanolin, Beeswax, Acacia,		
	Aids	Tragacanth, Sodium alginate,		
	Missallanas	Agar, Guar gum, Gelatine		
	Miscellaneous	Squill, Galls, Ashwagandha, Tulsi, Guggul		
6	Plant fibres used as sur	gical dressings: Cotton, silk, wool	3	CO3
	and regenerated fibres Sutures - Surgical Catgut	and Ligatures		17 52
	- Catalog Calgical Catgut	Sanjou	1. "	100

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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	CO4
8	Role of medicinal and aromatic plants in national economy and their export potential	2	CO5
9	Herbs as health food: Brief introduction and therapeutic applications of:	4	CO5
,	Nutraceuticals, Antioxidants, Pro-biotics, Pre-biotics, Dietary fibres, Omega-3-fatty acids, Spirulina, Carotenoids, Soya and Garlic		
10	Introduction to herbal formulations	4	CO5
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	CO5
12	Phytochemical investigation of drugs	2	CO2

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

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Practicals

1. Morphological Identification of the following drugs:

Ispaghula, Senna, Coriander, Fennel, Cardamom, Ginger, Nutmeg, Black Pepper, Cinnamon, Clove, Ephedra, Rauwolfia, Gokhru, Punarnava, Cinchona, Agar.

2. Gross anatomical studies (Transverse Section) of the following drugs:

Ajwain, Datura, Cinnamon, Cinchona, Coriander, Ashwagandha, Liquorice, Clove, Curcuma, Nux_vomica, Vasaka

3. Physical and chemical tests for evaluation of any FIVE of the following drugs:

Asafoetida, Benzoin, Pale catechu, Black catechu, Castor oil, Acacia, Tragacanth, Agar, Guar gum, Gelatine.

Assignments

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

- 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.

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HUMAN ANATOMY AND PHYSIOLOGY - THEORY

Course Code: FR20-14T

75 Hours (3 Hours/week)

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

Course Objectives: This course will discuss the following:

- 1. Structure and functions of the various organ systems and organs of the human body
- 2. Homeostatic mechanisms and their imbalances in the human body
- 3. Various vital physiological parameters of the human body and their significances

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

CO1: Describe the various organ systems of the human body

CO2: Discuss the anatomical features of the important human organs and tissues

CO3: Explain the homeostatic mechanisms regulating the normal physiology in the human system

CO4: Discuss the significance of various vital physiological parameters of the human body

CO5: Explain blood and its components with their functions and process of hemopoiesis, blood clotting and blood group.

Chapter	Topic	Hours	COs
1	Scope of Anatomy and Physiology	2	CO1
	Definition of various terminologies		
2	Structure of Cell: Components and its functions	2	CO2
3	Tissues of the human body: Epithelial, Connective, Muscular and Nervous tissues - their sub-types and characteristics.	4	CO3
4	Osseous system: structure and functions of bones of axial and appendicular skeleton	3	CO4
	Classification, types and movements of joints, disorders of joints	3	

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5	Haemopoietic system	8	CO5
	Composition and functions of blood		
	 Process of Hemopoiesis Characteristics and functions of RBCs, WBCs, 		
	and platelets		
	Mechanism of Blood Clotting		
	Importance of Blood groups		
6	Lymphatic system	3	CO1
	 Lymph and lymphatic system, composition, function and its formation. 		
	Structure and functions of spleen and lymph node.		
7	Cardiovascular system	8	CO2
	Anatomy and Physiology of heart	C	COZ
	Blood vessels and circulation (Pulmonary, coronary and		
	systemic circulation)		
	 Cardiac cycle and Heart sounds, Basics of ECG Blood pressure and its regulation 		
	•		
8	Respiratory system	4	CO3
	 Anatomy of respiratory organs and their functions. Regulation, and Mechanism of respiration. 		
	Respiratory volumes and capacities - definitions		
9	Digestive system	8	CO4
	Anatomy and Physiology of the GIT		
	Anatomy and functions of accessory glands Physiology of digastics and absorption		
	Physiology of digestion and absorption		
10	Skeletal muscles	2	CO5
	Histology Physical and a senting atting		
	Physiology of muscle contraction Disorder of skeletal muscles		
11	Nervous system	8	CO1
	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)		
12	Sense organs - Anatomy and physiology of	6	CO2
	• Eye		
	• Ear		
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13	 Urinary system Anatomy and physiology of urinary system Physiology of urine formation Renin - angiotensin system Clearance tests and micturition 	4	CO3
14	 Endocrine system (Hormones and their functions) Pituitary gland Adrenal gland Thyroid and parathyroid gland Pancreas and gonads 	6	CO4
15	 Reproductive system Anatomy of male and female reproductive system Physiology of menstruation Spermatogenesis and Oogenesis Pregnancy and parturition 	4	CO5

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HUMAN ANATOMY AND PHYSIOLOGY - PRACTICAL

Course Code: ER20-14P

75 Hours (3 Hours/week)

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

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

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

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

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

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Practicals

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

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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 (COs): Upon successful completion of this course, the students will be able to

CO1: Discuss about roles of pharmacists in the various national health programs

CO2: Describe various sources of health hazards and disease preventive measures

CO3: Discuss the healthcare issues associated with food and nutritional substances

CO4: Describe the general roles and responsibilities of pharmacists in public health

CO5: Discuss about the costs and outcomes associated with the use of pharmaceuticals in health care delivery

Chapter	Topic	Hours	Cos
1	Introduction to Social Pharmacy	9	CO1
	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) 		

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2	Preventive healthcare – Role of Pharmacists in the	18	CO2
	following		
	Demography and Family Planning (3)		
	Mother and child health, importance of breastfeeding, ill		
	effects of infant milk substitutes and bottle feeding (2)		
	(2)		
	Overview of Vaccines, types of immunity and		
	immunization (4)		
	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.	:4	
	Social Impact of these habits on social health and		
	productivity and suicidal behaviours (2)		
3	Nutrition and Health	10	CO3
	Basics of nutrition - Macronutrients and Micronutrients		
	(3)		
	Importance of water and fibres in diet (1)		
	Balanced diet, Malnutrition, nutrition deficiency diseases,		
PI	ill effects of junk foods, calorific and nutritive values of		
	various foods, fortification of food (3)		
	Introduction to food safety, adulteration of foods, effects		
	of artificial ripening, use of pesticides, genetically		
	modified foods (1)		
	Dietary supplements, nutraceuticals, food supplements		
	- indications, benefits, Drug-Food Interactions (2)		

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	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	CO4
5	Introduction to health systems and all ongoing National Health programs in India, their objectives, functioning, outcome, and the role of pharmacists.	8	CO1
6	Pharmacoeconomics - Introduction, basic terminologies, importance of pharmacoeconomics	2	CO5

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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):

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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

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Assignment

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

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

Field Visits

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

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

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8. ER-2020 D.Pharm Syllabus - Part II

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

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PHARMACOLOGY - THEORY

Course Code: ER20-21T 575 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 (COs): Upon successful completion of this course, the students will beable to

CO1: Describe the basic concepts of pharmacokinetics and pharmacodynamics.

CO2: Enlist the various classes and drugs of choices for any given disease condition

CO3: Advice the dosage regimen, route of administration and contraindications for a given drug

CO4: Describe the common adverse drug reactions

CO5: Discuss about biological agents and types, and indications of biological agents with examples

Chapter	Topic	Hours	Cos
1	General Pharmacology	10	CO1
	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 	m	upl
	Excretion of drugs - Definition, routes of drug excretion	VWIN	, , , , , , , , , , , , , , , , , , ,
	General mechanisms of drug action and factors modifying drug		

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	action		
2	Drugs Acting on the Peripheral Nervous System	11	CO2
	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		
Ø	g) Local anaesthetic agents		
	h) Non-Steroidal Anti-Inflammatory drugs		
	(NSAIDs)		
3	Drugs Acting on the Eye	2	CO3
	Definition, classification, pharmacological actions, dose,		
	indications and contraindications of		
	Miotics		
	Mydriatics		
	Drugs used in Glaucoma		
4	Drugs Acting on the Central Nervous System	8	CO4
	Definition, classification, pharmacological actions, dose,		
	indications, and contraindications of		
	General anaesthetics		
100	Hypnotics and sedatives		
	Anti-Convulsant drugs		
	Anti-anxiety drugs		
	Anti-depressant drugs		
	Anti-psychotics		
	Nootropic agents		
	Centrally acting muscle relaxants		
	Opioid analgesics		
5	Drugs Acting on the Cardiovascular System	6	CO5
	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	Drugs Acting on Blood and Blood Forming Organs ,	Λ	CQ1

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	Definition, classification, pharmacological actions, dose,		
	indications, and contraindications of		
	Hematinic agents		
	Anti-coagulants		
	Anti-platelet agents		
7	Thrombolytic drugs		
7	Definition, classification, pharmacological actions, dose,	2	CO2
	indications, and contraindications of		
	Bronchodilators —		
	Expectorants		
-	Anti-tussive agents		
	Mucolytic agents		
8	Drugs Acting on the Gastro Intestinal Tract	5	CO3
	Definition, classification, pharmacological actions, dose,		
	indications, and contraindications of		
	Anti-ulcer drugs		
	Anti-emetics		
	Laxatives and purgatives		
	Anti-diarrheal drugs		
9	Drugs Acting on the Kidney	2	CO4
	Definition, classification, pharmacological actions, dose,		
	indications, and contraindications of		
	Diuretics Anti Diuretics		
10	Anti-Diuretics Hormones and Hormone Antagonists	8	CO5
10	Physiological and pathological role and clinical uses of	0	003
	Thyroid hormones		
	Anti-thyroid drugs		
	Parathormone		
	C STANKE PARTIES A RELIGIOUS CONTRACTORS		
	Calcitonin Vitaggia B		
	Vitamin D		
	• Insulin		
	Oral hypoglycemic agents		
	• Estrogen		
	 Progesterone 		
	 Oxytocin 		
4.4	Corticosteroids		
11	Autocoids	3	CO1
	 Physiological role of Histamine, 5 HT and 		
1	Prostaglandins		
	Classification, clinical uses, and adverse effects of antibiotecrains and 5 LT agree register.		A
canes	antihistamines and 5 HT antagonists San Jew 80	awa	
	- San El VO	1-0-1	/

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	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-fungal drugs Anti-amoebic agents Anti-malarial agents Anti-meoplastic agents Anti-neoplastic agents	2	CO3
13	Biologicals Definition, types, and indications of biological agents with examples	2	003

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PHARMACOLOGY - PRACTICAL

Course Code: ER20-21P

50 Hours (2 Hours/week)

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

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

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

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

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

Practicals

Introduction to the following topics pertaining to the 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 about the state of the experiments. given. The given experiments shall be carried- out / demonstrated as the case may Registrar 43|Page

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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
- 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

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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 (COs): Upon successful completion of this course, the students will beable to

CO1: Describe the establishment, legal requirements, and effective administration of a community pharmacy

CO2: Professionally handle prescriptions and dispense medications

CO3: Counsel patients about the disease, prescription and or non-prescription medicines

CO4: Perform basic health screening on patients and interpret the reports in the community pharmacy settings

CO5: Manage a community pharmacy effectively, adhering to legal and ethical guidelines.

	Community Pharmacy Practice – Definition, history and	2	CO1
1			
1	development of community pharmacy - International and Indian scenarios		
	Professional responsibilities of community pharmacists	3	CO2
1	Introduction to the concept of Good Pharmacy Practice and SOPs.		
1 1	Prescription and prescription handling	7	CO3
	 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 jkstrategies to minimize them Sample And Control Cont		P

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4	Communication skills	6	CO4
	Definition, types of communication skills		
S.	 Interactions with professionals and patients 		
	 Verbal communication skills (one-to-one, over the 		
	telephone)		
	Written communication skills		
ži,	Body language		
0.	Patient interview techniques		
5	Patient counselling	10	CO3
	Definition and benefits of patient counselling		
	Stages of patient counselling - Introduction, counselling		
	content, counselling process, and closing the counselling		
	session		
	 Barriers to effective counseling - Types and strategies 		
	to overcome the barriers		
	 Patient counselling points for chronic 		
	diseases/disorders - Hypertension, Diabetes, Asthma,		
	Tuberculosis, Chronic obstructive pulmonary disease, and		
	AIDS		
	 Patient Package Inserts - Definition, i mportance and 		
*	benefits, Scenarios of PPI use in India and other countries		
	 Patient Information leaflets - Definition and uses 		
6	Medication Adherence	2	CO1
	Definition, factors influencing non-adherence, strategies to		
	overcome non-adherence		
7	Health Screening Services in Community Pharmacy	5	CO4
	Introduction, scope, and importance of various health screening		
	services - for routine monitoring of patients, early detection, and		
	referral of undiagnosed cases		
8	Over The Counter (OTC) Medications	15	CO3
	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)		
		Am	1

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9	Community Pharmacy Management		
3	 Legal requirements to set up a community pharmacy 	25	CO5
	Site selection requirements		
	Pharmacy designs and interiors		
	Vendor selection and ordering		
	Procurement, inventory control methods, and inventory management		
	management		
	Financial planning and management		
	 Accountancy in community pharmacy - Day book, Cash book 		
	 Introduction to pharmacy operation softwares - usefulness and availability 		
	Customer Relation Management (CRM)		
	Audits in Pharmacies		
	SOP of Pharmacy Management		
	 Introduction to Digital Health, mHealth and Online pharmacies 		dan tina

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

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Practicals

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

- 1. Handling of prescriptions with professional standards, reviewing prescriptions, checking for legal compliance and completeness (minimum 5)
- 2. Identification of drug-drug interactions in the prescription and follow-up actions (minimum 2)
- 3. Preparation of dispensing labels and auxiliary labels for the prescribed medications (minimum 5)
- 4. Providing the following health screening services for monitoring patients / detecting new patients (one experiment for each activity)

Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement

- 5. Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease) Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
- 6. Providing counselling to simulated patients for the following minor ailments (any three) Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
- 7. Appropriate handling of dummy dosage forms with correct administration techniques oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
- 8. Use of Community Pharmacy Software and digital health tools

Assignments

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

1. SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)

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- 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
- 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.

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BIOCHEMISTRY & CLINICAL PATHOLOGY - THEORY

Course Code: ER20-23T

75 Hours (3 Hours/week)

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

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

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

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

CO1: Describe the functions of biomolecules

CO2: Discuss the various functions of enzymes in the human system

CO3: Explain the metabolic pathways of biomolecules in both physiological and pathological conditions

CO4: Describe the principles of organ function tests and their clinical significances

CO5: Determine the biomolecules / metabolites in the given biological samples,

both qualitatively and quantitatively, describe the clinical pathology of blood and urine

Chapter	Topic	Hours	COs
1	Introduction to biochemistry: Scope of biochemistry in	2	CO1
	pharmacy; Cell and its biochemical organization.		
2	Carbohydrates	5	CO2
(1) and	 Definition, classification with examples, chemical properties 		
	 Monosaccharides - Structure of glucose, fructose, and galactose 		
	 Disaccharides - structure of maltose, lactose, and sucrose 		
a l	 Polysaccharides - chemical nature of starch and glycogen 		
	Qualitative tests and biological role of carbohydrates	and	

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3	Proteins	5	CO3
	 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. 		
4	Lipids	5	CO4
	 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	Nucleic acids	4	CO5
	 Definition, purine and pyrimidine bases Components of nucleosides and nucleotides with examples Structure of DNA (Watson and Crick model), RNA and 		
	their functions		
6	their functions Enzymes Definition, properties and IUB and MB classification Factors affecting enzyme activity Mechanism of action of enzymes, Enzyme inhibitors Therapeutic and pharmaceutical importance of	5	CO5
7	their functions 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 Vitamins	5	CO5
	 their functions 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 		CO1
	 their functions 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 Vitamins Definition and classification with examples Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins Metabolism (Study of cycle/pathways without chemical 		
7	 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 Vitamins Definition and classification with examples Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins 	6	CO1

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	level. Diseases related to abnormal metabolism of		
₩.	Carbohydrates		
	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,	05	CO3
	recommended dietary requirements		
10	Water and Electrolytes	05	CO4
	 Distribution, functions of water in the body 		
	Water turnover and balance		
	 Electrolyte composition of the body fluids, Dietary 		
	intake of electrolyte and Electrolyte balance		
(90)	 Dehydration, causes of dehydration and oral 		
	rehydration therapy		
11	Introduction to Biotechnology	01	CO5
		06	CO5
12	Organ function tests	UO	CO3
	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	0.0	004
13	Introduction to Pathology of Blood and Urine	06	CO1
	 Lymphocytes and Platelets, their role in health and 		
	disease		
	Erythrocytes - Abnormal cells and their significance		
	 Normal and Abnormal constituents of Urine and their 		
	significance		

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BIOCHEMISTRY & CLINICAL PATHOLOGY - PRACTICAL

Course Code: ER20-23P

50 Hours (2 Hours/week)

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

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

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

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

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

Practicals

- 1. Qualitative analysis of carbohydrates (4 experiments)
- 2. Qualitative analysis of Proteins and amino acids (4 experiments)
- 3. Qualitative analysis of lipids (2 experiments)
- 4. Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
- 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)
- 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 studen

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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 (COs): Upon successful completion of this course, the students will beable to

CO1: Help assessing the subjective and objective parameters of patients in common disease conditions

CO2: Assist other healthcare providers to analyse drug related problems and provide therapeutic interventions

CO3: Participate in planning the rational medicine therapy for common diseases

CO4: Design and deliver discharge counselling for patients

CO5: Management of the women's reproductive disorder. (Pharmacological and Non Pharmacological).

Chapter	Topic	Hours	COs
1	Pharmacotherapeutics - Introduction, scope, and objectives.	8	CO1
	Rational use of Medicines, Evidence Based Medicine,		
	Essential Medicines List, Standard Treatment Guidelines		
	(STGs)		
2	Definition, etiopathogenesis, clinical manifestations, ne	on-	CO ₂
	pharmacological and pharmacological management of	f	
	The diseases associated with		
	(a) Cardiovascular System		
	Hypertension	8	
	Angina and Myocardial infarction		
	Hyperlipidaemia		
	Congestive Heart Failure		
,	(b) Respiratory System	Zį.	
	Asthma		
	• COPD		
		P [±]	
	 (c) Endocrine System Diabetes Thyroid disorders - Hypo and Hyperthyroidism 	5)
	• Diabetes Scenier On	awy	
	Thyroid disorders - Hypo and Hyperthyroidism		

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	(d) Central Nervous System	8	
	Epilepsy		
	Parkinson's disease		
	Alzheimer's disease		
	Stroke		
	Migraine		
	(e) Gastro Intestinal Disorders	8	CO3
	Gastro oesophageal reflux disease		
	Peptic Ulcer Disease		
	Alcoholic liver disease		
	 Inflammatory Bowel Diseases (Crohn's Disease and 		
	Ulcerative Colitis)		
*	(f) Haematological disorders	4	
	Iron deficiency anaemia		
	Megaloblastic anaemia		
	(g) Infectious diseases	12	
	Tuberculosis		
	Pneumonia		
	Urinary tract infections		
	Hepatitis		
	Gonorrhoea and Syphilis		
	Malaria		
	HIV and Opportunistic infections		
	Viral Infections (SARS, CoV2)		
	(h) Musculoskeletal disorders	3	
¥	Rheumatoid arthritis		
	Osteoarthritis		
	(i) Dermatology	3	
	• Psoriasis		
	Scabies		
	Eczema		
	(j) Psychiatric Disorders	4	-
	Depression		
	Anxiety		
	Psychosis		
	(k) Ophthalmology	2	
	Operation attributes (In a stantial and viscal)		
	Glaucoma		
	(I) Anti-microbial Resistance	2	CO4
193	(m) Women's Health		
		4	CO5
	 Polycystic Ovary Syndrome Dysmenorrhea Premenstrual Syndrome 		
	Premenstrual Syndrome Sanjew W	many	

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PHARMACOTHERAPEUTICS - PRACTICAL

Course Code: ER20-24P

25 Hours (1 Hour/week)

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

Course Objectives: This course will train the students on

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

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

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

Practicals

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

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- II. Patient counselling exercises using role plays based on the real / hypothetical clinical case scenarios. The students are expected to provide counselling on disease condition, medications, life-style modifications, monitoring parameters, etc. and the same shall be documented. (Minimum 5 cases)
- III. Simulated cases to enable dose calculation of selected drugs in paediatrics, and geriatrics under various pathological conditions. (Minimum 4 cases)

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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 (COs): Upon successful completion of this course, the students will be able to

CO1: Explain about the basic concepts of hospital pharmacy administration, Poisoning, and radio Pharmaceuticals

CO2: Manage the supply chain and distribution of medicines within the hospital settings, and application of computers

CO3: Assist the other healthcare providers in monitoring drug therapy and address drug related problems, medications errors and clinical pharmacy

CO4: Interpret common lab investigation reports for optimizing drug therapy

CO5: Identify and prevent medication-related errors through pharmacovigilance and risk management strategies to enhance patient safety, Clinical laboratory tests used in the evaluation of disease states.

S. No.	Topic	Hours	COs
1	Hospital Pharmacy		CO1
	 Definition, scope, national and international scenario 	6	
	 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	awg	0
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2	Different Committees in the Hospital	4	CO1
	 Pharmacy and Therapeutics Committee - Objectives, 		
	Composition, and functions		
	 Hospital Formulary - Definition, procedure for 		
	development and use of hospital formulary		
	Infection Control Committee - Role of Pharmacist in		
	preventing Antimicrobial Resistance	# 0 TO THE REAL PROPERTY OF THE PROPERTY OF THE REAL PROPERTY OF THE REAL PROPERTY OF THE PRO	
3	Supply Chain and Inventory Control	14	CO2
	 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.	0 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
	 Inventory Management of Central Drug Store - Storage 	40000	
	conditions, Methods of storage, Distribution, Maintaining		
,	Cold Chain, Devices used for cold storage (Refrigerator,	The same and the s	
	ILR, Walk-in-Cold rooms)		
	FEFO, FIFO methods		
	- to the set to set the set the set of the second Disposed		
	Expiry drug removal and nandling, and disposal. Disposal of Narcotics, cytotoxic drugs		
1	Documentation - purchase and inventory Drug distribution		CO2
7	 Drug distribution (in- patients and out - patients) - 	1	
	Definition, advantages and disadvantages of individual		
	prescription order method, Floor Stock Method, Unit Dose	a contact of the cont	
		•	
	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		
E	storage Compounding in Hospitals. Bulk compounding, IV admixture	4	CO5
5	services and incompatibilities, Total parenteral nutrition	-	000
	Services and incompatibilities, Total parenteral management		
6	Radio Pharmaceuticals - Storage, dispensing and disposal of	2	CO1
_	radiopharmaceuticals	The state of the s	
7	Application of computers in Hospital Pharmacy Practice,	2	CO2
′	Electronic health records, Softwares used in hospital pharmacy		

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8	Clinical Pharmacy: Definition, scope, and development - in India and other countries	12	CO3
	Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Antinatal Care, Post-natal Care, etc.		
9	 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 	2	CO4
	pharmaceutical care Medication Therapy Management, Home Medication Review	40	CO5
10	 Clinical laboratory tests used in the evaluation of diseasestates - significance and interpretation of test results Haematological, Liver function, Renal function, thyroidfunction tests Tests associated with cardiac disorders Fluid and electrolyte balance Pulmonary Function Tests 	10	COS
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	CO1
12	Pharmacovigilance • Definition, aim and scope Overview of Pharmacovigilance	2	CO5
13	Medication errors: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP	6	CO3
*	Drug Interactions: Definition, types, clinical significance of drug interactions		

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HOSPITAL AND CLINICAL PHARMACY - PRACTICAL

Course Code: ER20-25P

25 Hours (1 Hour / Week)

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

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

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

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

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

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

Practicals

- 1. Systematic approach to drug information queries using primary / secondary / tertiary resources of information (2 cases)
- 2. Interpretation of laboratory reports to optimize the drug therapy in a given clinical case (2 cases)
- 3. Filling up IPC's ADR Reporting Form and perform causality assessments using various scales (2 cases)
- 4. Demonstration / simulated / hands-on experience on the identification, types, use / application /administration of

 Orthopaedic and Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc.

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- 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.

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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 (COs): Upon successful completion of this course, the students will be able to

CO1: Describe the history and evolution of pharmacy law in India

CO2: Interpret the act and rules regulating the profession and practice of pharmacy in India

CO3: Discuss the various codes of ethics related to practice standards in pharmacy

CO4: Interpret the fundamentals of patent laws from the perspectives of pharmacy

CO5: Discuss pharmaceutical Pricing and their policy

Chapter	Topics	Hours	COs
1	General Principles of Law, History and various Acts related	2	CO1
	to Drugs and Pharmacy profession		
2	Pharmacy Act-1948 and Rules: Objectives, Definitions,	5	CO2
	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		
3	Drugs and Cosmetics Act 1940 and Rules 1945 and New	2 3	CO2
	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.		
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	Supplements		
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	CO3
7	Poisons Act-1919 : Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	2	CO2
	Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.		000
6	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of Certain advertisements, Classes of Exempted advertisements, Offences and Penalties. Prevention of Cruelty to Animals Act-1960: Objectives,	2	CO2
4	Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	2	CO2
	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.		
	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.		

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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	CO5
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	CO3
11	Medical Termination of Pregnancy Act and Rules - basic understanding, salient features, and Amendments	2	CO2
12	Role of all the government pharma regulator bodies - Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	1	CO2
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	CO3
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	CO4
15	Blood bank - basic requirements and functions	2	CO2
16	Clinical Establishment Act and Rules - Aspects related to Pharmacy	2	CO2
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	CO2
18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	2	CO3
19	Introduction to the Consumer Protection Act	1	CO4
20	Introduction to the Disaster Management Act	1	CO3
21	Medical Devices - Categorization, basic aspects related to manufacture and sale	2	CO2
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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

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9. Appendices

No	Appendix Document	
1.	A typical format for the assessment of an Assignment	
2.	A typical format for the assessment of a Field Visit Report	
3.	List of instruments and equipment required for the conduct of D.Pharm	
	program as per ER-2020	

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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 <u>evaluation</u>, 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.

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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)
19	
	,
Drier proporation of the student for the	field visite (minimum 100 words)
Prior preparation of the student for the	neid visit. (minimum 100 words)
Describe the general experiences during	g the field visit: (minimum 100 words)
Learning points: Describe what theoret	ical concept that is correlated during
the field visit: (minimum 300 words)	
and field viola (imministing odd trotter)	

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Appendix - 3

List of Instruments and Equipment required for the Conduct of D.Pharm program as per ER-2020

As per ER 2020 regulation;

At least four laboratories specified below should be provided for:

- 1. Pharmaceutics Lab.
- 2. Pharm. Chemistry Lab.
- 3. Physiology, Pharmacology and Pharmacognosy Lab.
- 4. Biochemistry, Clinical Pathology, Hospital and Clinical Pharmacy Lab.

The institutions shall provide "Model Pharmacy" as per following details

Model Pharmacy	No.	Area
Essential: Running Model Community Pharmacy	01	80 Sq. Mts. (Including 10 Sq. mt. for Drug Information Centre & 10 Sq. mt. for Patient Counselling)
<u>Desirable</u> :		
Drug Model Store		

NOTE: Wherever animal experimentations are prescribed in the curriculum, the required knowledge and skill should be imparted by using computer assisted modules. Animal hold area shall be as per the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines.

Practical of Social Pharmacy, Pharmacotherapeutics can be conducted in any one of the laboratories by making necessary provisions.

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<u>Department wise List of Minimum Equipment required for D.Pharm</u> (For a practical batch of 20 students)

1. Physiology, Pharmacology and Pharmacognosy Lab.

S. No.	Name	Minimum required Nos. for D.Pharm 60 intake
1	Microscopes	20
2	Haemocytometer with Micropipettes	20
3	Sahli's haemoglobinometers	20
4	Sphygmomanometers	5
5	Stethoscopes	10
6	Human Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands
7	Models for various organs	One model of each organ system
. 8	Specimen for various organs and systems	One model for each organ system
9	Human Skeleton and bones	One set of skeletch and one spare bone
10	Different Contraceptive Devices and Models	One set of each device
11	Digital Balance (10 mg Sensitivity)	1
12	Computer with LCD	1
13	Licensed Software packages for Physiological & Pharmacological experiment	1
14	IR Thermometer	2
15	Refrigerator	1
16	First aid equipment	Adequate number
17	Stop watch	20
18	Dummy Inhalers and Nebulizer	1
19	Pharmacotherapeutic charts for various diseases & disorders	Adequate number
20	Surgical devices and Sutures	Adequate number
21	Digital BP Instrument	5
22	Mercury Thermometer	10
23	Digital Thermometer	10
24	Pulse Oximeter	5
25	ESR Apparatus (Westergren and Wintrobe)	10
26	Peak Flow meter	10
27	Stadiometer	2
28	Adult Weighing Scale (150 kg)	5
29	Glucometer	10
30	Projection microscope	1
31	Permanent slide set of plants and charts for Pharmacognosy Lab	Adequate number
32	Drug information resources	Adequate number
33	Various types of PPE Kits,	: Adequate number

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34	Charts /displays/ AVs on tobacco control, glycemic index of foods, nutrition, reproductive health	Adequate number
35	Menstrual hygiene products	Adequate number
36	Display for various disinfectants, mosquito repellents etc	Adequate number
37	Water Testing Kit	Adequate number
38	Permanent slide of different microbes	Adequate number

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

2. Pharmaceutical Chemistry/ Biochemistry, Clinical Pathology

		for D.Pharm 60 intake
1	Hot plates	5
2	Hot Air Oven	1
3	Refrigerator	1
4	Analytical Balances for demonstration	1
5	Digital balance 10mg sensitivity	5
6	Magnetic Stirrers with Thermostat	10
7	Vacuum Pump	1
8	Digital pH meter	1
9	Wall Mounted Water Distillation Unit	2
10	Nessler's Cylinders	40
11	Digital Melting Point Apparatus	2
12	Thieles Tube	20
13	Digital Colorimeter	2
14	Thermostatic Water Bath	11

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

3. Pharmaceutics

S. No.	Name	Minimum required Nos. for D.Pharm 60 intake
1	Digital balance (10mg)	5
2	Microscopes	10
3	Autoclave	1
4	Vacuum Purap	1
5	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 54, 60, 80, 85, 100, 120	10 sets
6	Tablet dissolution test apparatus IP (Digital single/double Unit)	1
7	Magnetic stirrer, 500ml and 1 litter capacity with speed control	5

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8	Digital pH meter	1
9	Capsule Counter	2
10	Hot Plate	2
11	Distillation Unit	1
12	Tablet counter - small size	2
13	Hot air oven	1
14	Electric water bath unit	2
15	Stalagmometer	5
16	Desiccator	5
17	Buchner Funnels (Medium)	10
18	Filtration assembly with Vacuum Pump	1
19	Andreasen's Pipette	5
20	Ointment slab	20
21	Ointment spatula	20
22	Pestle and mortar porcelain	20
23	Refrigerator	1
24	Micrometre slide Eyepiece	5
25	Micrometre slide Stage	5
26	Viscometer Ostwald/Brookfield	1
27	Stop watch	11
28	Sintered glass filter with vacuum	4
	The second secon	

NOTE: Aseptic cabinet or area should be provided as per Appendix A of ER 2020 Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

Machine Room

S. No.	Name	Minimum required Nos. for D.Pharm 60 intake
1	Capsule filling machine	. 1
2	Automated Single Station Tablet punching machine	1
3	Tablet disintegration test apparatus IP (Digital Single/Double unit)	1
4	Monsanto's hardness tester	2
5	Pfizer type hardness tester	2
6	Friability test apparatus (Digital Single/Double unit)	1
7	Sieve shaker with sieve set	1
8	Ointment filiing machine	1
9	All-purpose equipment with all accessories	1
10	Bottle washing Machine	1
11	Bottle Sealing Machine	1
12	Liquid Filling Machine	1
13	Ampoule washing machine	
14	Ampoule filling and sealing machine (Jet Burner)	Projection 1803 CM

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15	Clarity test apparatus	1
16	Collapsible tube - Filling and Sealing	11
17	Liquid Mixer	1

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

4. Hospital and Clinical Pharmacy Lab

S. No.	Name	Minimum required Nos for D.Pharm 60 intake
1	Orthopaedical & Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc	Adequate Number
2	Different Types of bandages such as sterile gauze, cotton, crepe bandages, roll bandage etc	Adequate Number
3	Mannequins for CPR ·1 (with indication Signals)	2
4	Mannequins for injection IV Arm	2
5	Variety of Needles	20
6	Variety of Syringes	20
7	Variety of catheters	5
8	IV set	20
9	Urine Bag	2
10	RYLE's tube	2
11	Urine pots	2
12	Colostomy bags	2
13	Oxygen masks	10
14	Inventory Software for Retail Pharmacy	

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

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5. Model Pharmacy

S. No.	Name	Minimum required Nos. for D.Pharm 60 intake
	 Empty cartons of variety medicines (across variety dosage forms) Various name plates indicating different parts of Pharmacy, Proper arrangement of medicines, shelves, racks, drawers Box/area for expiry medicines, Display windows, shelves Computer Refrigerator Designated patient counselling area, Patient Information Leaflets/Cards Patient waiting area, Drug Information books Health information display, Various devices for screening services (B.P. monitor, glucometer etc) Height and body weight chart Dummy devices (eg. Inhalers) Display of pharmacist registration, license and other licenses Display of name of owner Inspection book, Lock and key arrangement for Schedule X and NDPS medicines, Bill book (dummy) , Computer stationary for bill printing 	Adequate
2	Computers: hospital and community pharmacy management software	1

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APPENDIX 4

Subject wise list of Recommended Books (Latest Edition)

Pharmaceutics

- 1. History of Pharmacy in India by Dr. Harikishan Singh
- 2. Indian Pharmacopoeia, Govt. of India Publication
- **3.** A Text book of Pharmaceuticals Formulation by B.M. Mithal, Vallabra 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.F. 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 Fress Ltd, Manipal
- 7. Augmented Text Book of Homeopathic Pharmacy by Dr. D D Banerjee, B Jain Publishers (P) Ltd

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Human Anatomy and Physiology

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

Social Pharmacy

- 1. Social Pharmacy Innovation and development. Geoff Harding, Sarah Nettleton and Kevin Taylor. The Pharmaceutical Press.
- 2. Text Book of Community Pharmacy Practice. RPSGB Publication
- 3. Community Pharmacy Handbook- Jonathan Waterfield
- 4. S Khurana, P Suresh and R Kalsi. Health Education & Community Pharmacy. S Vikas & Co
- 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
- Where There Is No Doctor: A Village Health Care Handbook by David Werner ,2015 updated version
- 10. Various WHO publications www.who.int

Pharmacology

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- **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

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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 PharmaSoS, Drugs in Special population- Pregnancy and Lactation, Tobacco free future- Choice is yours: KSPC Publications.
- 9. Responsible Use of Medicines: A Layman's Handbook, <u>www.ipapharma.org</u> /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.

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Hospital and Clinical Pharmacy

- 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 Frakashan.
- 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 E.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

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