

Sanjay Ghodawat University

Kolhapur

Established under section 2(f) of UGC act 1956 Sanjay Ghodawat University Act XL of 2017 of Govt. of Maharashtra

Empowering Lives Globally!

School of Pharmaceutical Sciences

S. Y. D. Pharm.

Curriculum

Academic Year 2022-23

The Education Regulations, 2020 for Diploma Course in Pharmacy (D. Pharm), Pharmacy Council of India.

Rules & Syllabus (framed under Regulation 7, under Appendix-A of The Education Regulations, 2020) for the Diploma in Pharmacy (S. Y. D. Pharm) Course

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SANJAY GHODAWAT UNIVERSITY KOLHAPUR

Sanjay Ghodawat University (SGU) is established in the Academic Year 2017-18, as a State Private University under Govt. of Maharashtra Act No. XL of 2017 dated 3rd May 2017, with the approval of the UGC and the State Government. "For the true measure of giving is giving without measure." Spread across 150 Acres, Sou. Sushila Danchand Ghodawat Charitable Trust's Sanjay Ghodawat University (SGU) is situated in a serene atmosphere amidst idyllic hills and lush green meadows to study in harmony with Nature. The Institution aspires to run along the lines of best-in-the-world education and become a world-class institution where the teaching-learning process gets a far deeper meaning. SGUalways stands as the guiding star of brilliance, quality, and deliverance beyond expectations. Innovativeness and Creativity are the hallmarks of a genius enterprise and SGU stands to be a stage where these qualities would be nurtured, encouraged, and blossomed. The genius is incomplete without the sense of social responsibility and SGU's ultimate goal remains the development of an attitude of gratitude that freely gives back without expectations. The Sanjay Ghodawat University stands as a beacon of light to guidethe younger generation of the day on the right path to fulfillment in career and life. The USP of the University is its research-based curriculum and academically-oriented teaching staff. The world-class ambiance and infrastructure help the students to easily accommodate themselves in an environment that is conducive to the teaching-learning process. Hands-on experience, challenge-based case studies, maximum participation of students in the classroom, use of modern digital technology, smart classrooms, solution-oriented thinking promotion, stress on research and innovation, international tie-ups, choice-based credit system for flexibility in choosing areas of interest, etc. are some of the features of the University. The university will help students develop as unique individual-to be educated as a whole person, intellectually, emotionally, socially, ethically, and spiritually. The educational program designs are worked out meticulously in line with best in class universities with a special focus on:

- ➤ Flexible Choice Based Credit System
- ➤ OBE Outcome Based Education System
- Experiential Learning
- Project-Based Learning
- Case-Based Learning
- Training need analysis based on Performance Appraisal System
- Active Learning tools for effective delivery
- Mentoring / Proctorship
- Online learning /Self-learning platforms
- Flipped Classroom concept
- Effective Student Feedback Mechanism

SCHOOL OF PHARMACEUTICAL SCIENCES

Vision

To be recognized as the to pharmaceutical education provider in the region by imparting high level of academic and research outcomes which are aligned with better regional and global needs.

Mission

M 1 – Outcomes based quality education:

To provide outcomes based quality education to produce competent and ethical pharmacy professionals to face emerging challenges of the globalized pharmaceutical industry.

M2-Research and lifelong learning:

To establish the strong industry connections, develop research profile and lifelong learning to optimize adequate care and healthcare delivery.

M3-Inculcating values and ethics:

To inculcate the professional ethics and human values in pharmacy professionals and developing them to serve the healthcare needs of society.

M4- Fostering leadership qualities:

To provide conducive environment to boost the practical skills, entrepreneur traits and leadership qualities in budding pharmacists to stay ahead in the competitive world.

CORE VALUES

- Integrity
- Transparency
- Accountability
- **Equality**
- **Empathy**
- Stewardship

QUALITY POLICY

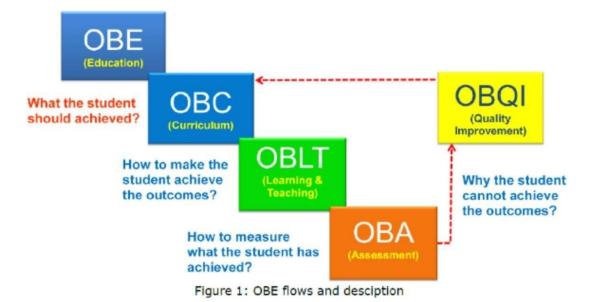
Sanjay Ghodawat University is committed to establish high standards in value-based quality education to enhance and nurture young minds to excel in their chosen profession and develop into socially responsible citizens through resourceful collaboration, innovationand research

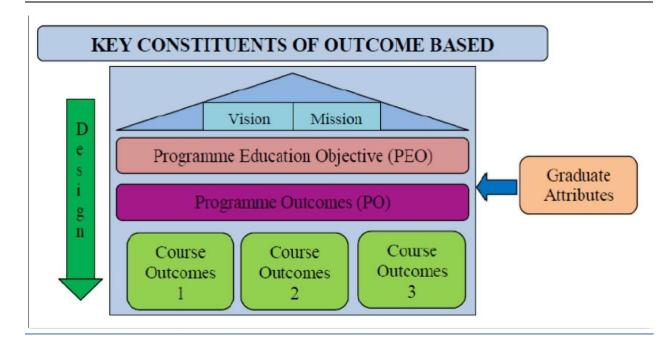
OUTCOME BASED EDUCATION (OBE) MODEL

Sanjay Ghodawat University (SGU) has implemented OBE model of education, which is a learner-centered approach. SGU has witnessed a sea change in the entire academic system with the implementation of all three components of OBE - Design, Delivery, and Assessment. The SGU model of autonomy focuses on experiential learning which beliefs in learning by doing. This is achieved through hands-on experience, industrial assignments, mini-projects, and live problem solving and collaboration with industries.

SGU is set into dynamics of transformation and witnessing a shift in focus from teaching to learning and the entire academic system of SGU is designed to provide multiple learning opportunities for students to acquire and demonstrate the Knowledge, Skills, and Attitudes (KSA) for rewarding career. The Vision and Mission of the Management, the contribution from eminent BOG members and knowledgeable members of Academic Council and Board of Studies, the motivation and drive of the Director, the relentless efforts of the fellow Deans and Head of Departments and all teaching and non-teaching staff along with a commitment to the learning of students made it possible to successfully transform the institute and stand out to carve a niche for itself as an Institute of repute.

OBE is an approach to curriculum design and teaching that focuses on what students should be able to do (attained) at the end of the course/program. Outcome-based education(OBE) is a student-centered instruction model that focuses on measuring student performance through outcomes. Outcomes include knowledge, skills, and attitudes (KSA). Its focus remains on the evaluation of outcomes of the program by stating the knowledge, skill and behavior a graduate is expected to attain upon completion of a program and after 4 – 5 years of graduation. In the OBE model, the required knowledge and skillsets for a particular degree are predetermined and the students are evaluated for all the required parameters (Outcomes) during the program.





The OBE model measures the progress of the graduate in three parameters, which are

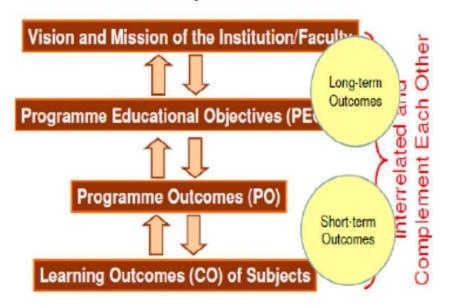
- Program Educational Objectives (PEO)
- Program Outcomes (PO)
- Course Outcomes (CO)

Program Educational Objectives (PEO) are broad statements that describe the career and professional accomplishments that the program is preparing the graduates to achieve. PEO"s are measured 4-5 years after graduation. Program outcomes are narrower statements that describe what students are expected to know and be able to do by the time of graduation. They must reflect the Graduate attributes. Course outcomes are the measurable parameters that evaluate each student's performance for each course that the student undertakes every semester.

The various assessment tools for measuring Course Outcomes include Tests and End Semester Examinations, Tutorials, Assignments, Project work, Labs, Presentations, Employer/Alumni Feedback, etc. These course outcomes are mapped to Graduate attributes and Program outcomes based on relevance. This evaluation pattern helps Institutions to measure the Program Outcome. The Program Educational Objective is measure through Employer satisfaction survey (Yearly), Alumni survey (Yearly), Placement records, and higher education records.

Outcomes in OBE

A Model Hierarchy of Outcomes



Special Features of OBE

- OBE is an educational process that focuses on what students can do or the qualities they should develop after they are taught.
- OBE involves the restructuring of curriculum, assessment, and reporting practices in education to reflect the achievement of high order learning and mastery rather than accumulation of course credits.
- Both structures and curricula are designed to achieve those capabilities or qualities.
- Discourages traditional education approaches based on direct instruction of facts and standard methods.
- It requires that the students demonstrate that they have learned the required skills and content.

About D. Pharm course:

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.

SR2. Competencies for the Indian D. Pharm Holders (Program Outcome)

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 Developmen
- 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 / nonprescription medicines and other health related issues. Effective communication includes using both oral and written communication skills and various communication techniques.
- 4. **Hospital and Community Pharmacy Management:** The student should be able to manage the drug distribution system as per the policies and guidelines of the hospital pharmacy, good community pharmacy practice and the recommendations of regulatory agencies. Also, be able to manage the procurement, inventory, and distribution of medicines in hospital / community pharmacy settings.
- 5. Expertise on Medications: The student should be able to provide an expert opinion on

- medications to health care professionals on safe and effective medication-use, relevant policies and procedures based on available evidences.
- 6. **Proficiency on Pharmaceutical Formulations:** The student should be able to describe the chemistry, characteristics, types, merits and demerits of both drugs and excipients used in pharmaceutical formulations based on her/his knowledge and scientific resources.
- 7. **Entrepreneurship and Leadership:** The student should be able to acquire the entrepreneurial skills in the dynamic professional environments. Also, be able to achieve leadership skills through teamwork and sound decision- making skills.
- 8. **Deliver Primary and Preventive Healthcare:** The student should be able to contribute to various healthcare programs of the nation including disease prevention initiatives to improve public health. Also contribute to the promotion of national health policies.
- 9. Professional, Ethical and Legal Practice: The student should be able to deliver professional services in accordance with legal, ethical, and professional guidelines with integrity.
- 10. Continuing Professional Development: The student should be able to recognize the gaps in the knowledge and skills in the effective delivery of professional services from time to time and be self-motivated to bridge such gaps by attending continuing professional development programs.

SR3. Competency Mapping with the Courses (Part I, II & III) of ER 2020

Сол	npetencies (POs)	Pharmaceutics	Pharmaceutical Chemistry	Pharmacognosy	Human Anatomy & Physiology	Social Pharmacy	Pharmacology	Community Pharmacy & Management	Biochemistry & Clinical Pathology	Pharmacotherapeutics	Hospital & Clinical Pharmacy	Pharmacy Law & Ethics	Practical training
1.	Review Prescriptions	V	$\sqrt{}$		V			V	1	1	V	V	$\sqrt{}$
2.	Dispense Prescription / Non- Prescription Medicines							$\sqrt{}$	$\sqrt{}$	$\sqrt{}$		$\sqrt{}$	
3.	Provide Patient Counselling / Education	1	V		V	$\sqrt{}$	V	V	1	1		V	V
4.	Hospital and Community Pharmacy Management					1		$\sqrt{}$				1	1
5.	Expertise on Medications	$\sqrt{}$	$\sqrt{}$		1	$\sqrt{}$		V	1	$\sqrt{}$	1	V	
6.	Proficiency on pharmaceutical formulations	V	V				V			1			1
7.	Entrepreneurship and Leadership							$\sqrt{}$			$\sqrt{}$		1
8.	Deliver Primary and Preventive Healthcare				V	V	1	V	V	$\sqrt{}$	V	V	V
9.	Professional, Ethical and Legal Practice					1		V		1	V	V	V
10	Continuing Professional Development	V	V			1	V	V		1	V	V	√

CHAPTER-I:

REGULATIONS

The Education Regulations, 2020 for Diploma Course in Pharmacy Regulations made under section 10 of the Pharmacy Act, 1948. (As approved by the Government of India, Ministry of Health & Family Welfare vide letter No. Z-28020/59/2019- AHS/FTS-8012809 dated 7.10.2020 and notified by the Pharmacy Council of India.)

ER. CHAPTER: 1

R1. Short title and commencement-

- (1) These regulations may be called the Education Regulations, 2020 for Diploma course in Pharmacy.
- (2) They shall come into force on the date of their publication in the official Gazette.

R2. Qualification for Pharmacist-

The minimum qualification required for registration as a pharmacist shall be a pass in Diploma in Pharmacy (Part-I & Part-II) and satisfactory completion of Diploma in Pharmacy (Part-III).

Or

Any other qualification approved by the Pharmacy Council of India as equivalent to the above.

R3. Diploma in Pharmacy (Part-I, Part-II and Part-III):

Shall consist of a certificate of having completed the course of study and passed the examination after satisfactory completing the practical training as prescribed in Chapter-2 and Chapter-3 of these regulations.

ER. CHAPTER: 2

R4. Diploma in Pharmacy (Part-I and Part-II)-

Minimum qualification for admission to Diploma in Pharmacy-A pass in 10+2 examination (science academic stream) with Physics, Chemistry and Biology or Mathematics. or

Any other qualification approved by the Pharmacy Council of India as equivalent to the above examination. Provided that there shall be reservation of seats for the Scheduled Castes and the Scheduled Tribes candidates in accordance with the instructions issued by the Central Government /State Governments /Union territory administrations as the case may be from time to time.

R5. Duration of the course-

- [1] The duration of the course shall be for two academic years. Each academic year shall be spread over a period of not less than one hundred and eighty working days.
- [2] In addition there shall be a five hundred hours of practical training spread over a period of not less than three months.

R6. Course of study-

The course of study for Diploma in Pharmacy Part-I and Diploma in Pharmacy Part-II shall include the subjects as given in the Tables I & II below. The number of hours devoted to each subject for its teaching in Theory and Practical, shall not be less than that noted against it in columns 2 and 3 of the Tables below. However, the course of study and practical training may be modified by the Pharmacy Council of India from time to time.

Table-I. Diploma in Pharmacy Part-I

Name of the course	Theory	Practical	Tutorial
Pharmaceutics	75	75	25
Pharmaceutical Chemistry	75	75	25
Pharmacognosy	75	75	25
Human Anatomy & Physiology	75	75	25
Social Pharmacy	75	75	25
Total	375	375	125

Table-II. Diploma in Pharmacy Part-II

Table 11. Diploma in 1 nat macy 1 art 11						
Name of the course	Theory	Practical	Tutorial			
Pharmacology	75	50	25			
Community Pharmacy & Management	75	75	25			
Biochemistry & Clinical Pathology	75	50	25			
Pharmacotherapeutics	75	25	25			
Hospital and Clinical Pharmacy	75	25	25			
Pharmacy Law & Ethics	75		25			
Total	450	225	150			

Table-III. Diploma in Pharmacy Part-III

Tuble III. Diploma in I nur mucy I ur t III								
	Activities	Hr/activity	Total Hrs					
1)	Stocking of Drugs and Medical Devices		Practical Training –					
2)	Inventory Control Procedures		500 hours					
3)	Handling of prescriptions							
4)	Dispensing	(250 hours)						
5)	Patient counseling							

R7. Syllabus-

The syllabus for each subject of study shall be as prescribed by the Pharmacy Council of India from time to time.

SR-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 students will be orient by the teacher 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 will 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. This will 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 will 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 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 total hours of any given chapter can be distributed among the sub-topics as required by the subject matter.

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

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 hourenables 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 assignment topics will be selected 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 widen the horizons of knowledge and broadening the scope of the syllabus. Every student shall submit a report describing their objectives, experience, learning points, etc. pertaining to the field trip, in the typical format given in Appendix-2.

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

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

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

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".

R9. Examinations:

- 1) There shall be an annual examination at the end of the academic year.
- 2) If necessary, there shall be a supplementary examination for the students who are not able to pass Diploma in Pharmacy Part-I or Part-II, as the case may be, as per the criteria specified by the examining authority.
- 3) The examinations shall be of written and practical (including viva voce) nature, carrying maximum marks for each part of a subject, as indicated in Table IV and V below.

Table-IV. Diploma in Pharmacy Part-I Examination

Name of the course	Theory (Maximum Marks)			Practical (Maximum Marks)		
	SE	EAE	Total	SE	EAE	Total
Pharmaceutics	20	80	100	20	80	100
Pharmaceutical Chemistry	20	80	100	20	80	100
Pharmacognosy	20	80	100	20	80	100
Human Anatomy & Physiology	20	80	100	20	80	100
Social Pharmacy	20	80	100	20	80	100
Total			500			500

Table-V. Diploma in Pharmacy Part-II Examination

Name of the course	Theory (Maximum Marks)			Practical (Maximum Marks)		
	SE	EAE	Total	SE	EAE	Total
Pharmacology	20	80	100	20	80	100
Community Pharmacy & Management	20	80	100	20	80	100
Biochemistry & Clinical Pathology	20	80	100	20	80	100
Pharmacotherapeutics	20	80	100	20	80	100
Hospital and Clinical Pharmacy	20	80	100	20	80	100
Pharmacy Law & Ethics	20	80 .	100	=		=
Total			600			500

EAE = End Annual Exam; SE = Sessional Exam

Note: 75% attendance in theory and practical separately is compulsory to attend the examinations

R10. Eligibility for appearing at the Diploma in Pharmacy Part-I and Part II examination-

Only such candidates who produce certificate from the Head of the academic institution in which he/she has undergone the Diploma in Pharmacy Part-I and Part-II course in proof of his/her having regularly and satisfactorily undergone the course of study by attending not less than 75% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at the Diploma in Pharmacy (Part-I) or (Part II) examination, as the case may be.

R11. Mode of examinations-

- (1) Theory and Practical examination in the subjects mentioned in Tables IV & V shall be of three hours duration. Both Theory and Practical are considered as two separate papers.
- (2) A candidate who fails in theory or practical examination of a subject shall re-appear for the failed subject. Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.
- (3) Practical examination shall also consist of a viva-voce examination.

SR5. Theory examinations

Sessional Examinations (Theory):

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) (Multiple Choice	10 x 1=10
	Questions / Fill-in the Blanks /One word OR one Sentence questions)	
	Total marks	= 40

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

University Final Theory Examinations (Annual Theory Exam):

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

SR6. Practical examinations

Sessional Examinations (Practical):

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 (Major experiment = 30; Minor experiment/spotter etc = 20)	= 50*
III.	Viva voce	= 10
IV.	Practical Record Maintenance	= 10
	Total marks	= 80
	Converted to	= 10

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 marks	= 20 marks
*, \$ Only for the courses given with both assignments and field visit/s	

Note:

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

University Final Practical Examinations (Annual Practical Exam):

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 (Major experiment = 35; Minor experiment/spotter etc = 25)	= 60*						
III.	Viva voce	= 10						
	Total marks	= 80						
	* 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							

SR. Appendix – 9

A typical format for the assessment of an Assignment

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

Directions: For evaluation, enter rating of the student utilizing the following scale:

5 – Excellent; 4 - Very Good; 3 – Good; 2 – Satisfactory; 1 – Poor

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

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

SR. Appendix - 10

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 o	ne by one)					
Prior preparation of the student for the field visit: (minir	mum 100 words)					
Describe the general experiences during the field visit: (minimum 100 words)						
Learning points: Describe what theoretical concept the (minimum 300 words)	at is correlated during the field visit:					

R12. Award of sessional marks and maintenance of records-

- (1) A regular record of both theory and practical class work and examinations held in an institution imparting training for Diploma in Pharmacy Part-I and Diploma in Pharmacy Part-II courses, shall be maintained for each student in the institution and 20 marks for each theory and 20 marks for each practical subject shall be allotted as sessional marks.
- (2) There shall be two or more periodic sessional (internal assessment) examinations during each academic year. The highest aggregate of any two performances shall form the basis of calculating sessional marks.
- (3) The sessional marks in practical shall be allotted on the following basis:-
- (i) Actual performance in the sessional / spacing examination = 10 marks.
- (ii) Day to day assessment in the practical class/spacing work =10 marks.

R13. Minimum marks for passing the examination –

A student shall not be declared to have passed Diploma in Pharmacy examination unless he/she secures at least 40% marks in each of the subjects separately in the theory as well as the practical examinations, including sessional marks.

The candidates securing 60% marks or above in aggregate in all subjects shall be declared to have passed in first class.

The candidates securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in that subject or those subjects.

The grant of first class and distinction shall be subject to the condition that the candidate shall pass all the subjects in a single attempt.

R14. Eligibility for promotion to Diploma in Pharmacy (Part-II)-

All candidates who have appeared for all the subjects and passed the Diploma in Pharmacy Part -I examination are eligible for promotion to the Diploma in Pharmacy Part-II class. However failure in more than two subjects shall debar him/her from promotion to Diploma in Pharmacy Part II class.

R15. Improvement of sessional marks-

The candidates who wish to improve sessional marks can do so, by appearing in two additional sessional examinations during the next academic year. The average score of the two examinations shall be the basis for improved sessional marks in theory as well as in practical. Marks awarded to a candidate for day to day assessment in the practical class cannot be improved unless he/she attends a regular course of study again.

R16. Approval of examinations-

The examinations mentioned in regulations 9 to 15 shall be held by an examining authority.

R17. Certificate of passing examination for Diploma in Pharmacy (Part-II)-

Certificate of having passed the examination for the Diploma in Pharmacy Part-II shall be granted by the examining authority to a successful student.

ER. CHAPTER-3

<u>Diploma in Pharmacy (Part-III) (Practical Training)</u>

R18. Period and other conditions for practical training-

- (1) After having appeared in Part-II examination for the Diploma in Pharmacy held by an approved Examining Authority a candidate shall be eligible to undergo practical training in one or more of the following institutions namely:
- (i) Hospitals/Dispensaries run by Central /State Governments.
- (ii) A pharmacy licensed for retail sale of drugs under the Drugs and Cosmetics Rules, 1945 having the services of registered pharmacists.
- (iii) Hospital and Dispensary other than those specified in sub-regulation (i) above for the purpose of giving practical training shall have to be recognized by Pharmacy Council of India on

fulfilling the conditions specified in Appendix-C to these regulations.

- (2) The institutions referred in sub-regulation (1) shall be eligible to impart training subject to the condition that number of student pharmacists that may be taken in any hospital, dispensary or pharmacy licensed under the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940, shall not exceed four where there is one registered pharmacist engaged in the work in which the student pharmacist is undergoing practical training, where there is more than one registered pharmacist similarly engaged, the number shall not exceed two for each additional such registered pharmacist.
- (3) In the course of practical training, the trainee shall have exposure to -
- (i) Working knowledge of keeping of records required by various Legislative Acts concerning the profession of pharmacy; and
- (ii) Practical experience in activities mentioned in Table III under regulation 6 of these regulations.
- (4) The practical training shall be not less than five hundred hours spread over a period of not less than three months provided that not less than two hundred and fifty hours are devoted to actual dispensing of prescriptions.

	Table III. Diploma in Pharmacy (Part III) Practical Training – 500 hours								
Activ	Activities								
1)	Stocking of Drugs and Medical Devices								
2)	Inventory Control Procedures								
3)	Handling of prescriptions								
4)	Dispensing (250 hours)								
5)	Patient counseling								

R19. Procedure to be followed prior to commencement of the training-.

- (1) The head of institution imparting practical training, on application, shall supply in triplicate 'Practical Training Contract Form for Pharmacist" (hereinafter referred to as the Contract Form) to the candidate eligible to undertake the said practical training. The Contract Form shall be as specified in Appendix-D to these regulations.
- (2) The head of institution imparting practical training shall fill Section I of the Contract Form. The trainee shall fill Section II of the said Contract Form and the head of the institution agreeing to impart the training (hereinafter referred to as the Apprentice Master) shall fill Section III of the said Contract form.
- (3) It shall be the responsibility of the trainee to ensure that one copy (hereinafter referred to as the first copy of the Contract Form) so filled is submitted to the head of institution imparting practical training and the other two copies (hereinafter referred to as the second copy and the third copy) shall be filed with the Apprentice Master (if he so desires) or with the trainee till completion of the training.

20. Certificate of passing Diploma in Pharmacy Part-III

On satisfactory completion of the practical training period the Apprentice Master shall fill Section IV of the second copy and third copy of the Contract Form and forward it to the head of institution imparting practical training who shall suitably enter in the first copy of the entries

from the second copy and the third copy and shall fill Section V of the three copies of Contract Form and thereafter hand over both the second copy and the third copy to the trainee.

This Contract Form, completed in all respects, shall be regarded as a certificate of having successfully completed the course of Diploma in Pharmacy (Part- III).

ER. CHAPTER-4

21. Certificate of Diploma in Pharmacy-

A certificate of Diploma in Pharmacy shall be granted by the examining authority to a successful candidate on producing certificates of having passed the Diploma in Pharmacy Part I and Part II and satisfactory completion of practical training for Diploma in Pharmacy (Part-III).

University Facilities, Rules and Regulations

1. Audit Course:

A student may have to register for an audit course in a D. Pharm Part-I or Part-II which could be an institute requirement or department requirement.

An audit course may include either a) a regular course required to be done as per structure or required as a pre-requisite of any higher-level course or b) the programs like practical training, industry visits, societal activities etc

Audit course shall not carry any credits but shall be reflected in Grade Card as "PP"/"NP" depending upon the satisfactory performance in the semester evaluation as per the course curriculum structure.

2. Facilitation to Students:

Faculty Advisor:

On joining the institute, a student or a group of students shall be assigned to a faculty advisor who shall be a mentor for a student throughout his/her tenure in the institute. A student shall be expected to consult the faculty advisor on any matter relating to his/her academic performance and the courses he/she may take in various semesters/summer term. A faculty advisor shall be the person to whom the parents/guardians should contact for performance-related issues of their ward.

The role of the Faculty Adviser is outlined below:

- a) Guide the students about the rules and regulations governing the courses of study for a particular degree.
- b) Advise the students for registering courses as per the curriculum given. For this purpose, the Faculty Adviser has to discuss with the student his/her academic performance during the previous semester and then decide the number and nature of the courses for which He / She can register during the semester as per the curriculum.
- c) Approve the registration of the students.
- d) Advice students to overload/ drop one or more courses/activities based on her/his academic performance as per the prescribed rules.

- e) At the end of the first semester/year, the Faculty Adviser may even advise a reduced load program for a poorly performing student.
- f) Pay special attention to weak students and carefully monitor the performance of students recommended for the slow track option.
- g) Advice students for Course Adjustment/Dropping of courses during the Semester within the stipulated time frame given in the Academic calendar.
- h) Advice students seeking semester drop either during the ongoing semester or before the commencement of the semester. FA has to ensure strict compliance with rules and regulations laid down for this purpose. Recommend the cases to the appropriate authorities for consideration.
- i) Make a revised plan of study for weak/bright students based on their semester-wise performance.
- j) Suggest modalities for course/credit requirements for the students recommended for the exchange program.
- k) Guidance and liaison with parents of students for their performance.
- 1) To ensure that students are not permitted to re-register for courses, which they have already passed.
- m) Inform students that any academic activity (course/Lab./seminar/project/noncredit requirement etc.) undergone without proper registration will not be counted towards the requirements of his/her degree.
- n) Strictly warn students that if she/he fails to register during any semester without prior approval, his/her studentship is liable to be canceled.
- o) Keep the students updated about the Academic Administration of the University.

2.2. Helping Weaker Students:

A student with backlog/s should continuously seek help from his/her faculty advisor, Head of the Department and the Dean of respective schools. Additionally, he/she must also be in constant touch with his/her parents/local guardians for keeping them informed about academic performance. The university also shall communicate to the parents/guardians of such student at-least once during each semester regarding his/her performance in various tests and examinations and also about his/her attendance. It shall be expected that the parents/guardians to keep constant touch with the concerned faculty advisor or Head of the Department, and if necessary - the Dean of the respective school.

3. Discipline and Conduct:

- Every student shall be required to observe discipline and decorous behavior both inside and outside the campus and not to indulge in any activity, which shall tend to bring down the prestige of the university.
- Any act of indiscipline of a student reported to the Dean, Student Development, shall be discussed in a Disciplinary Action Committee of the institute. The Committee shall enquire into the charges and recommend suitable punishment if the charges are substantiated.
- ➤ If a student while studying in the university is found indulging in anti-national

activities contrary to the provisions of acts and laws enforced by the Government, he/she shall be liable to be expelled from the institute without any notice.

- ➤ If a student is involved in any kind of ragging, the student shall be liable for strict action as per provisions in the Maharashtra anti-ragging act.
- ➤ If any statement/information supplied by the student in connection with his/her admission is found to be false/ incorrect at any time, his/ her admission shall be canceled and he/she shall be expelled from the university, and fees paid shall be forfeited.
- ➤ If a student is found guilty of malpractice in examinations, then he/she shall be punished as per the recommendations of the Grievance Redressal Committee (CRC) constituted by the Board of Examinations.
- Every admitted student shall be issued a photo identification (ID) card which must be retained by the student while he/she is registered at Sanjay Ghodawat University Kolhapur. The student must have a valid ID card with him/her while on the University Campus.
- Any student who alters or intentionally mutilates an ID card or who uses the ID card of another student or allows his/her ID card to be used by another, the student shall be subjected to disciplinary action.
- ➤ The valid ID card must be presented for identification purposes as and when demanded by authorities. Any student refusing to provide an ID card shall be subjected to disciplinary action.
- > Students should switch off the Mobiles during the Instructional hours and in the academic areas of the university Building, Library, Reading room etc. Strict action will be taken if students do not adhere to this.
- ➤ During the conduct of any Tests and Examinations, students must not bring their mobiles. A student in possession of the mobile whether in use or switched off condition will face disciplinary action and will be debarred from appearing for the Test / Examination.

4. Academic Calendar

The academic activities of the institute are regulated by Academic Calendar and is made available to the student's/ faculty members and all other concerned in electronic form or hard copy. It shall be mandatory for students/faculty to strictly adhere to the academic calendar for the completion of academic activities.

CHAPTER - II:

Second Year D. Pharm (Part-II) SYLLABUS

Diploma in Pharmacy (Part-II)

Course	Course Title	Com	ponent l	Hr/Year	Com	ponent	Hr/week	Exam	WT		Min Passing
Code		L	Т	P	L	Т	P				(%)
ER20-21T	Pharmacology –	75	25	-	3	1	-	Sessional- 1	40		
	Theory							Sessional- 2	40	20	40%
	(100 Marks)							Sessional- 3	40		4070
								EAE	80	80	
ER20-21P	Pharmacology –	-	-	50	-	-	2	Sessional- 1	80		40%
	Practical							Sessional- 2	80	10	
	(100 Marks)							Sessional- 3	80		
								Assignment-1	10	1.0	
								Assignment-2	10	10	
								Assignment-3	10	00	
EDOC OOT	0 4	75	25		3	1		EAE Sessional- 1	80 40	80	400/
ER20-22T	Community	/3	25	-	3	1	-	Sessional- 2	40	20	40%
	Pharmacy & Management –							Sessional- 3	40	20	
	Theory(100 Marks)							EAE	80	80	
ER20-22P	Community			75			3	Sessional- 1	80	00	40%
EK20-221	Pharmacy &	-	-	13	_	_	3	Sessional- 2	80	10	4070
	Management-							Sessional- 3	80	10	
	Practical							Assignment-1	05		
	(100 Marks)							Assignment-2	05	05	
	()							Assignment-3	05	03	
								FVR	05	05	
								EAE	80	80	
ER20-23T	Biochemistry & Clinical	75	25	_	3	1	_	Sessional- 1	40		40%
	Pathology –							Sessional- 2	40	20	
	Theory							Sessional- 3	40		
	(100 Marks)							EAE	80	80	
ER20-23P	Biochemistry & Clinical	-	-	50	-	-	2	Sessional- 1	80		40%
	Pathology –							Sessional- 2	80	10	
	Practical							Sessional- 3	80		
	(100 Marks)							Assignment-1	10		
								Assignment-2	10	10	
								Assignment-3	10		
								EAE	80	80	
ER20-24T	Pharmacotherapeutics	75	25	-	3	1	-	Sessional- 1	40		40%
	- Theory(100							Sessional- 2	40	20	
	Marks)							Sessional- 3	40		
								EAE	80	80	
ER20-24P	Pharmacotherapeutics	-	-	25	-	-	1	Sessional- 1	80		40%
	- Practical(100							Sessional- 2	80	20	
	Marks)							Sessional- 3	80	0.0	
******								EAE	80	80	4007
ER20-25T	Hospital & Clinical	75	25	-	3	1	-	Sessional- 1	40	20	40%
	Pharmacy –							Sessional 2	40	20	
	Theory (100 Marks)							Sessional- 3 EAE	40 80	80	
ED20.25D	Hospital & Clinical			25			1	Sessional- 1	80	οU	40%
ER20-25P	Pharmacy –	-	-	23	-	-	1	Sessional- 2	80	10	40%
	Practical							Sessional- 3	80	10	
	(100 Marks)							Assignment-1	05		
	(200 1/14/10)							Assignment-2	05	05	
								Assignment-3	05	05	
								FVR	05	05	
								EAE	80	80	
ER20-26T	Pharmacy Law &	75	25	-	3	1	_	Sessional- 1	40		40%
2.120 201	Ethics Theory (100 Marks)	15				1				20	.570
	, (Sessional- 2	40	-	
								Sessional- 3	40		
								EAE	80	80	
	Total									1100	400

EAE = End Annual Exam; FVR = Field Visit Report

Note: 75% attendance in theory and practical separately is compulsory to attend the examinations

DIPLOMA IN PHARMACY- PART II

With effect from: 2022-23 Duration: 32 weeks

		_		Cor H	mpon Ir/wee	ents ek						Exam	ination Schei	me						
Sr.	Course Course Abbreviati Course code	Course code							Theory						Practi	cal			Grand	
no.	Course Title	on	Course code	L	Т	P	Exam	TH		TM		Total		PR		PM		Total		Total
							Duration in Hrs.	Max Marks	Min Marks	Max Marks	Min Marks	Max Marks	Min Marks	Max Marks	Min Marks	Max Marks	Min Marks	Max Marks	Min Marks	
1	PHARMACOLOGY- Theory	PG T	ER20-21T	3	1	-	3	80	00	20*	00	100	40	-	-	-	-	-	-	100
2	PHARMACOLOGY - Practical	PG P	ER20-21P	-	-	2	3	-	-	-	-	-	-	80#	00	20*	00	100	40	100
3	COMMUNITY PHARMACY & MANAGEMENT- Theory	СРМ Т	ER20-22T	3	1	ı	3	80	00	20*	00	100	40	1	-	-	-	-	ı	100
4	COMMUNITY PHARMACY & MANAGEMENT - Practical	СРМ Р	ER20-22P	-	-	3	3	-	-	-	-	-	-	80#	00	20*	00	100	40	100
5	BIOCHEMISTRY & CLINICAL PATHOLOGY- Theory	ВСР Т	ER20-23T	3	1	-	3	80	00	20*	00	100	40	-	-	-	-	-	-	100
6	BIOCHEMISTRY & CLINICAL PATHOLOGY- Practical	ВСР Р	ER20-23P	-	-	2	3	-	-	-	-	-	-	80#	00	20*	00	100	40	100
7	PHARMACOTHERAPE UTICS- Theory	PT T	ER20-24T	3	1	-	3	80	00	20*	00	100	40	-	-	-	-	-	-	100
8	PHARMACOTHERAPE UTICS - Practical	PT P	ER20-24P	-	-	1	3	-	-	-	-	-	-	80#	00	20*	00	100	40	100
9	HOSPITAL & CLINICAL PHARMACY- Theory	НСР Т	ER20-25T	3	1	-	3	80	00	20*	00	100	40	-	-	-	-	-	-	100
10	HOSPITAL & CLINICAL PHARMACY -Practical	НСР Р	ER20-25P	-	-	1	3	-	-	-	-	-	-	80#	00	20*	00	100	40	100
11	PHARMACY LAW & ETHICS	PLE T	ER20-26T	3	1	-	3	80	00	20*	00	100	40	-	-	-	-	-	-	100
	Total	1		18	6	9	-	480	-	120	-	600	-	400	-	100	-	500	-	1100

Student Contact Hours Per Week: 33 Hrs

Theory and Practical periods of 60 minutes each.

Abbreviations: TH- Theory, PR- Practical, TM- Theory Sessional, PM, Practical Sessional, L- Lectures, T- Tutorial, P- Practical

External Assessment

*Internal Assessment

Candidate shall be declared as "detained" in case of not fulfilling the condition in regulation R10 as per ER2020 for Diploma Course in Pharmacy.

Program: Diploma in Pharmacy

Year: Second Year

Course Title: ER20-21T

Course Name: PHARMACOLOGY- THEORY

Chapter No	Chapter Title	Teaching Hours	Blooms T		-	as per
			Level	Understand Level	Apply Level	Total Marks
1	General Pharmacology	10	3	5	1	9
2	Drugs Acting on the Peripheral Nervous System	11	3	5	3	11
3	Drugs Acting on the Eye	02	2	-	-	02
4	Drugs Acting on the Central Nervous System	08	3	5	3	11
5	Drugs Acting on the Cardiovascular System	06	5	3	1	09
6	Drugs Acting on Blood and Blood Forming Organs	04	1	3	-	04
7	Definition, classification, pharmacological actions, dose, indications and contraindications of Bronchodilators, Expectorants, Anti-tussive agents, Mucolytic agents	02	3	-	1	03
8	Drugs Acting on the Gastro Intestinal Tract	05	-	5	1	06
9	Drugs Acting on the Kidney	02	-	3	1	04
10	Hormones and Hormone Antagonists	08	5	3	2	10
11	Autocoids	03	1	3	-	04
12	Chemotherapeutic Agents	12	5	5	3	13
13	Biologicals	02	2	-	-	02
	Total	75 Hours	33	40	15	88 Marks

Program: Diploma in Pharmacy

Year: Second Year

Course Title: ER20-22T

Course Name: COMMUNITY PHARMACY & MANAGEMENT- THEORY

Chapter No	Chapter Title	Teaching Hours	Distribution of Theory Marks as per Blooms Taxonomy					
	Title		Remember Level	Understand Level	Apply Level	Total Marks		
1	Community Pharmacy Practice	2	3	0	0	4		
2	Professional responsibilities of community pharmacists, concept of Good Pharmacy Practice and SOPs	3	2	3	0	5		
3	Prescription and prescription handling	7	2	5	2	9		
4	Communication skills	6	3	3	0	6		
5	Patient counselling	10	4	4	3	11		
6	Medication Adherence	2	1	2	0	4		
7	Health Screening Services in Community Pharmacy	5	1	2	2	5		
8	Over The Counter (OTC) Medications	15	4	6	6	16		
9	Community Pharmacy Management	25	20	10	5	28		
	Total	75 Hours	40	35	23	88 Marks		

Program: Diploma in Pharmacy

Year: Second Year

Course Title: ER20-23T

Course Name: BIOCHEMISTRY & CLINICAL PATHOLOGY-THEORY

Chapter No	Chapter Title	Teaching Hours	Distribution of Theory Marks as per Blooms Taxonomy					
110	Title	Hours	Remember Level	Understand Level	Apply Level	Total Marks		
1	Introduction to biochemistry	2	2	0	0	2		
2	Carbohydrates	5	2	4	0	6		
3	Proteins	5	0	4	3	7		
4	Lipids	5	0	4	2	6		
5	Nucleic acids	4	0	4	1	5		
6	Enzymes	5	2	3	2	7		
7	Vitamins	6	2	4	0	6		
8	Metabolism	20	6	12	4	22		
9	Minerals	5	0	2	1	3		
10	Water and Electrolytes	5	2	3	1	6		
11	Introduction to Biotechnology	01	0	1	1	2		
12	Organ function tests	06	3	4	2	9		
13	Introduction to Pathology of Blood and Urine	06	2	5	0	7		
	Total	75 Hours	21	50	17	88 Marks		

Program: Diploma in Pharmacy

Year: Second Year

Course Title: ER20-24T

Course Name: PHARMACOTHERAPEUTICS-THEORY

Chapter No	Chapter Title	Teaching Hours		stribution of as per Bloom		omy
			Remember Level	Understand Level	Apply Level	Total Marks
1	Pharmacotherapeutics – Introduction, scope and objectives. Rational use of medicines, evidence based medicines, essential medicines list, standard treatment guidelines (STGs)	8	3	3	0	6
2 2a	Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with Cardiovascular System Hypertension					
	Angina and Myocardial infarction Hyperlipidaemia Congestive Heart Failure	8	5	3	2	10
2b	Respiratory System Asthma COPD	4	3	2	0	5
2c	Endocrine System Diabetes Thyroid disorders - Hypo and Hyperthyroidism	5	3	3	0	6
2d	Central Nervous System Epilepsy Parkinson's disease Alzheimer's disease Stroke Migraine	8	5	3	2	10

2e	Gastro Intestinal Disorders					
	Gastro oesophageal reflux disease					
	Peptic Ulcer Disease	8	5	3	2	10
	Alcoholic liver disease	8	3	3	2	10
	Inflammatory Bowel					
	Diseases (Crohn's Disease					
	and Ulcerative Colitis)					
2f	Haematological disorders					
4 1	Iron deficiency anaemia	4	3	0	1	4
	Megaloblastic anaemia	T	3	V	1	
2g	Infectious diseases					
2 8	Tuberculosis					
	Pneumonia					
	Urinary tract infections					
	Hepatitis	12	5	6	4	15
	Gonorrhoea and Syphilis					
	Malaria					
	HIV and Opportunistic infections					
	Viral Infections (SARS, CoV2)					
2h	Musculoskeletal disorders					
	Rheumatoid arthritis	3	3	0	0	3
	Osteoarthritis					
2i	Dermatology					
	Psoriasis	3	3	0	0	3
	Scabies					
	Eczema					
2j	Psychiatric Disorders					
	Depression	4	3	2	0	5
	Anxiety					
	Psychosis					
2k	Ophthalmology					
	Conjunctivitis (bacterial	2	3	0	0	3
	and viral)					
	Glaucoma					
21	Anti-microbial Resistance	2	0	3	0	3
2m	Women's Health					
	Polycystic Ovary	4	3	2	0	5
	Syndrome Dysmenorrhea					
	Premenstrual					
	Syndrome					
	Total	75 Hours	47	30	11	88 Marks

Program: Diploma in Pharmacy

Year: Second Year

Course Title: ER20-25T

Course Name: HOSPITAL & CLINICAL PHARMACY- THEORY

Chapter No	Chapter Title	Teaching Hours	Distribution of Theory Marks as per Blooms Taxonomy			
	Title		Remember Level	Understand Level	Apply Level	Total Marks
1	Hospital Pharmacy	6	3	5	2	10
2	Different Committees in the Hospital	4	4	2	0	6
3	Supply Chain and Inventory Control	14	6	6	2	14
4	Drug distribution	7	6	3	0	9
5	Compounding in Hospitals.	4	2	2	0	4
6	Radio Pharmaceuticals	2	2	2	0	4
7	Application of computers in Hospital Pharmacy Practice,	2	0	2	1	3
8	Clinical Pharmacy: Daily activities of clinical pharmacist, Pharmaceutical care, Medication therapy Management, Home medication review	12	3	6	3	12
9	Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results	10	2	3	4	9
10	Poisoning: Drugs and Poison Information Centre and their services	6	3	4	0	7
11	Pharmacovigilance	2	1	1	0	2
12	Medication errors, Drug Interactions	6	3	3	2	8
	Total	75 Hours	35	39	14	88 Marks

Program: Diploma in Pharmacy

Year: Second Year

Course Title: ER20-26T

Course Name: PHARMACY LAW & ETHICS-THEORY

Chapter No	Chapter Title	Teaching Hours	Distribution of Theory Marks as per Blooms Taxonomy			
			Remember Level	Understand Level	Apply Level	Total Marks
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2	2	1	0	3
2	Pharmacy Act-1948 and Rules	5	3	2	0	5
3	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments	23	10	10	7	27
4	Narcotic Drugs and psychotropic substances Act 1985 and Rules	2	3	0	0	3
5	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954	2	2	1	0	3
6	Prevention of cruelty to Animals Act-1960	2	1	1	0	2
7	Poisons Act-1919	2	2	1	0	3
8	FSSAI (Food Safety and Standards Authority of India) Act and Rules	2	1	0	0	1
9	National Pharmaceutical Pricing Authority	5	3	2	2	7
10	Code of Pharmaceutical Ethics	5	3	3	0	6
11	Medical Termination of Pregnancy Act and Rules	2	2	1	1	4

		Hours				wiarks
	Total	75	43	32	13	88 Marks
21	Medical devices	2	1	0	0	1
20	Introduction to the Disaster Management Act	1	0	1	0	1
19	Introduction to the Consumer Protection Act	1	0	1	0	1
18	Bioethics	2	2	1	0	3
17	Biomedical Waste Management Rules 2016	2	0	1	0	1
16	Clinical Establishment Act and Rules -Aspects related to Pharmacy	2	2	1	0	3
15	Blood bank – basic requirements and functions	2	0	1	0	1
14	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA,	7	3	3	2	8
13	Good Regulatory practices	3	2	1	1	4
12	Role of all the government pharma regulator bodies	1	1	0	0	1

ER20-21T. PHARMACOLOGY (Theory)

75 Hours (3 Hours/week)

Course	Course Title		Hours		Component	Exam	WT		Passing
Code		L	T	P	•				Min. (%)
ER20-	Pharmacology	3/wk	1/wk	-	Theory	Sessional-1	40		
21T.	(Theory)	75/yr	25/yr		(100 Marks)	Sessional-2	40	20	40%
						Sessional-3	40		4070
						EAE	80	80	

Course Content:

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:

- CLO1. **Describe** the basic concepts of pharmacokinetics and pharmacodynamics
- CLO2. Enlist the various classes and drugs of choices for any given disease condition
- CLO3. **Advice** the dosage regimen, route of administration and contraindications for a given drug
- CLO4. **Describe** the common adverse drug reactions

CH		Topic	Hours
1.	General Pharmacology		10

- Introduction and scope of Pharmacology
- Various routes of drug administration advantages and disadvantages
- Drug absorption definition, types, factors affecting drug absorption
- Bioavailability and the factors affecting bioavailability
- Drug distribution definition, factors affecting drug distribution
- Biotransformation of drugs Definition, types of biotransformation reactions, factors influencing drug metabolisms
- Excretion of drugs Definition, routes of drug excretion

General mechanisms of drug action and factors modifying drug action

2. **Drugs Acting on the Peripheral Nervous System**

11

- 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
 - Neuromuscular blocking agents e)
 - f) Drugs used in Myasthenia gravis
 - Local anaesthetic agents g)
 - h) Non-Steroidal Anti-Inflammatory drugs (NSAIDs)

3. **Drugs Acting on the Eye**

2

Definition, classification, pharmacological actions, dose, indications and contraindications of

- **Miotics**
- **Mydriatics**
- Drugs used in Glaucoma

4. **Drugs Acting on the Central Nervous System**

8

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- General anaesthetics
- Hypnotics and sedatives
- Anti-Convulsant drugs
- Anti-anxiety drugs
- Anti-depressant drugs
- Anti-psychotics
- Nootropic agents
- Centrally acting muscle relaxants
- Opioid analgesics

5. **Drugs Acting on the Cardiovascular System**

6

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Anti-hypertensive drugs
- Anti-anginal drugs
- Anti-arrhythmic drugs
- Drugs used in atherosclerosis and

	<u>α</u>	1 ,	C '1
•	Congesti	ve heart	tailure

• Drug therapy for shock

6. Drugs Acting on Blood and Blood Forming Organs

4

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Hematinic agents
- Anti-coagulants
- Anti-platelet agents
- Thrombolytic drugs

7. Definition, classification, pharmacological actions, dose, indications, and contraindications of

2

- Bronchodilators
- Expectorants
- Anti-tussive agents
- Mucolytic agents

8. Drugs Acting on the Gastro Intestinal Tract

5

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

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Diuretics
- Anti-Diuretics

10. Hormones and Hormone Antagonists

8

Physiological and pathological role and clinical uses of

- Thyroid hormones
- Anti-thyroid drugs
- Parathormone
- Calcitonin
- Vitamin D
- Insulin
- Oral hypoglycemic agents
- Estrogen
- Progesterone

Oxytocin

Corticosteroids

11. Autocoids

3

- Physiological role of Histamine, 5 HT and Prostaglandins
- Classification, clinical uses, and adverse effects of antihistamines and 5 HT antagonists

12. Chemotherapeutic Agents:

12

Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication and contraindications of drugs belonging to following classes:

- Penicillins
- Cephalosporins
- Aminoglycosides
- Fluoroquinolones
- Macrolides
- Tetracyclines
- Sulphonamides
- Anti-tubercular drugs
- Anti-fungal drugs
- Anti-viral drugs
- Anti-amoebic agents
- Anthelmintics
- Anti-malarial agents
- Anti-neoplastic agents

13. Biologicals

2

Definition, types, and indications of biological agents with examples

Recommended Books

- 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

ER20-21P. PHARMACOLOGY (Practical)

50 Hours (2 Hours/week)

Course	Course Title		Hou	rs	Component	Exam	WT		Passing
Code		L	T	P	1				Min.(%)
ER20-	Pharmacology	-	-	2/ wk	Practical	Sessional- 1	80		
21P	(Practical)			50/yr	(100 marks)	Sessional- 2	80	10	
						Sessional- 3	80		
						Assignment-1	10		40%
						Assignment-2	10	10	7070
						Assignment-3	10		
						EAE	80	80	

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

- **CLO1. Study** and report the local anaesthetic, mydriatic and mitotic effects of the given drug on the rabbit eye
- **CLO2.** Choose appropriate animal experiment model to study the effects of the given drugs acting on the central nervous system and submit the report
- **CLO3. Perform** the effects of given tissues (simulated) on isolated organs / tissues and interpret the results
- **CLO4. Interpret** the dose dependent responses of drugs in various animal experiment models

No. Practicals

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

- 1. Introduction to experimental pharmacology
- 2. Study of laboratory animals
 - (a) Mice; (b) Rats; (c) Guinea pigs; (d) Rabbits

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- 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

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

- 7. Study of local anaesthetics on rabbit eye
- 8. Study of Mydriatic effect on rabbit eye
- 9. Study of Miotic effect on rabbit eye
- Effect of analgesics using Analgesiometer 10.
- Study of analgesic activity by writhing test 11.
- 12. Screening of anti-convulsant using Electro Convulsiometer
- 13. Screening of Muscle relaxants using Rota-Rod apparatus
- 14. Screening of CNS stimulants and depressants using Actophotometer
- 15. Study of anxiolytic activity using elevated plus maze method
- 16. Study of effect of drugs (any 2) on isolated heart
- Effect of drugs on ciliary motility on frog"s buccal cavity 17.
- 18. Pyrogen testing by rabbit method

Assignments

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

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

Recommended Books

- 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

ER20-22T. COMMUNITY PHARMACY & MANAGEMENT (Theory)

75 Hours (3 Hours/week)

Course	Course Title		Hours		Component	Exam	WT		Passing
Code		L	T	P					Min. (%)
ER20-	Community	3/wk	1/wk	-	Theory	Sessional-1	40		
22T.	Pharmacy &	75/yr	25/yr		(100 Marks)	Sessional-2	40	20	40%
	Management					Sessional-3	40		4070
	(Theory)					EAE	80	80	

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:

- **CLO1. Describe** the establishment, legal requirements, and effective administration of a community pharmacy
- CLO2. Professionally handle prescriptions and dispense medications
- **CLO3.** Counsel patients about the disease, prescription and or non-prescription medicines
- **CLO4. Perform** basic health screening on patients and interpret the reports in the community pharmacy settings

СН	Торіс	Hours
1.	Community Pharmacy Practice:	2
	Definition, history and development of community pharmacy - International and Indian scenarios	
2.	Professional responsibilities of community pharmacists	3
	Introduction to the concept of Good Pharmacy Practice and SOPs.	

3. Prescription and prescription handling 7 Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them 4. **Communication skills** 6 Definition, types of communication skills Interactions with professionals and patients Verbal communication skills (one-to-one, over the telephone) Written communication skills Body language Patient interview techniques 5. **Patient counselling** 10 Definition and benefits of patient counselling Stages of patient counselling - Introduction, counselling content, counselling process, and closing the counselling session Barriers to effective counseling - Types and strategies to overcome the barriers Patient counselling points for chronic diseases/disorders – Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS Patient Package Inserts - Definition, importance and benefits, Scenarios of PPI use in India and other countries **Patient Information leaflets -** Definition and uses 6. **Medication Adherence** 2 Definition, factors influencing non- adherence, strategies to overcome non-adherence 5 7. **Health Screening Services in Community Pharmacy** Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases 15 8. **Over The Counter (OTC) Medications** Definition, need and role of Pharmacists in OTC medication dispensing

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- 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)

9. **Community Pharmacy Management**

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

Recommonded Books:

- 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 PharmaceuticalPress
- 5. Comprehensive Pharmacy Review Edt. Leon Shargel. Lippincott Williams andWilkins.
- 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 ofMedicines: Layman"s Handbook, www.ipapharma.org /publications
- 10. Community Pharmacy Practice Globe: around the Part One: www.ipapharma.org /publications

25

ER20-22P. COMMUNITY PHARMACY & MANAGEMENT (Practical)

75 Hours (3 Hours/week)

Course	Course Title		Hou	irs	Component	Exam	WT		Passing
Code		L	T	P					Min. %)
ER20-	Community	-	-	3/wk	Practical	Sessional- 1	80		
22P	Pharmacy &			75/yr	(100 marks)	Sessional- 2	80	10	
	Management					Sessional- 3	80		
	(Practical)					Assignment-1	05		40%
						Assignment-2	05	05	
						Assignment-3	05		
						FVR	05	.05	
						EAE	80	80	

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

- **CLO1. Handle** and fill prescriptions in a professional manner
- **CLO2.** Counsel patients on various diseases and minor ailments
- CLO3. Counsel patients on prescription and or non-prescription medicines
- CLO4. Design and prepare patient information leaflets
- **CLO5. Perform** basic health screening tests

Note: The following practical 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.

No.	Experiment
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
- 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,
- 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

Skin infections, Oral and dental disorders.

Assignments

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

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

- 14. Community Pharmacy Practice Standards: Global Vs. Indian Scenario
- 15. Overview of pharmacy associations in India

Field Visit

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

Recommonded Books:

- 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 PharmaceuticalPress
- 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/ byMoH/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, www.ipapharma.org
- 10. Community Pharmacy Practice around the Globe: Part One: www.ipapharma.org

ER20-23T. BIOCHEMISTRY & CLINICAL PATHOLOGY (Theory)

Theory (75 Hours)

Course	Course Title		Hours		Component	Exam	WT		Passing
Code		L	T	P					Min. (%)
ER20-	Biochemistry &	3/wk	1/wk	-	Theory	Sessional-1	40		
23T.	Clinical	75/yr	25/yr		(100 Marks)	Sessional-2	40	20	40%
	Pathology					Sessional-3	40		4076
	(Theory)					EAE	80	80	

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:

- **CLO1. Describe** the functions of biomolecules
- **CLO2.** Discuss the various functions of enzymes in the human system
- **CLO3. Explain** the metabolic pathways of biomolecules in both physiological and pathological conditions
- CLO4. Describe the principles of organ function tests and their clinical significances
- **CLO5. Determine** the biomolecules / metabolites in the given biological samples, both qualitatively and quantitatively
- CLO6. Describe the clinical pathology of blood and urine

СН	Торіс	Hours
1.	Introduction to biochemistry: Scope of biochemistry in pharmacy;	2
	Cell and its biochemical organization.	
2.	Carbohydrates	5
	 Definition, classification with examples, chemical properties 	
	Monosaccharides - Structure of alucose fructose and galactose	

Disaccharides - structure of maltose, lactose, and sucrose Polysaccharides - chemical nature of starch and glycogen Qualitative tests and biological role of carbohydrates 3. **Proteins** 6 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. 5 Lipids Definition, classification with examples Structure and properties of triglycerides (oils and fats) Fatty acid classification – Based on chemical and nutritional requirements with examples Structure and functions of cholesterol in the body Lipoproteins - types, composition and functions in the body Qualitative tests and functions of lipids 5. **Nucleic acids** 4 Definition, purine and pyrimidine bases Components of nucleosides and nucleotides with examples Structure of DNA (Watson and Crick model), RNA and their functions 6. 5 **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 7. Vitamins 6 Definition and classification with examples Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins 8. Metabolism 20

(Study of cycle/pathways without chemical structures)

Metabolism of Carbohydrates: Glycolysis, TCA cycle and glycogen

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	metabolism, regulation of blood glucose 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	5
	Types, Functions, Deficiency diseases, recommended dietary requirements	
10.	Water and Electrolytes	5
	 Distribution, functions of water in the body 	
	 Water turnover and balance 	
	 Electrolyte composition of the body fluids, Dietary intake of electrolyte and Electrolyte balance 	
	Dehydration, causes of dehydration and oral rehydration therapy	
11.	Introduction to Biotechnology	1
12.	Organ function tests	6
	 Functions of kidney and routinely performed tests to assess the functions of kidney and their clinical significances 	
	 Functions of liver and routinely performed tests to assess the functions of liver and their clinical significances 	
	 Lipid profile tests and its clinical significances 	
13.	Introduction to Pathology of Blood and Urine	6
	 Lymphocytes and Platelets, their role in health and disease 	
	 Erythrocytes - Abnormal cells and their significance 	
	 Normal and Abnormal constituents of Urine and their significance 	
Recomm	onded Books:	

- 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.

ER20-23P. BIOCHEMISTRY & CLINICAL PATHOLOGY (Practical)

75 Hours (3 Hours/week)

Course	Course Title	Но		urs	Component	Exam	WT		Passing
Code		L	T	P					Min.(%)
ER20-	Biochemistry &	-	-	2/wk	Practical	Sessional- 1	80		
23P	clinical			50/yr	(100 marks)	Sessional- 2	80	10	
	Pathology					Sessional- 3	80		
	(Practical)					Assignment-1	10		40%
						Assignment-2	10	10	7070
						Assignment-3	10		
						EAE	80	80	

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

CLO1. Qualitatively determine the biomolecules / metabolites in the given biological samples **CLO2. Determine** the normal and abnormal constituents in blood and urine samples and interpret the results of such testing

No.	Practicals
1.	Qualitative analysis of carbohydrates (4 experiments)
2.	Qualitative analysis of Proteins and amino acids (4 experiments)
3.	Qualitative analysis of lipids (2 experiments)
4.	Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
5.	Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)
6.	Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
7.	Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

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

Recommonded Books:

- 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

ER20-24T. PHARMACOTHERAPEUTICS (Theory)

75 Hours (3 Hours/week)

Course	Course Title	Hours			Component	Exam	WI		Passing
Code		L	T	P					Min. (%)
ER20-	Human Anatomy	3/wk	1/wk	-	Theory	Sessional-1	40		
24T.	and Physiology	75/yr	25/yr		(100 Marks)	Sessional-2	40	20	40%
	(Theory)					Sessional-3	40		4070
	, , ,					EAE	80	80	

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:

- **CLO1. Help** assessing the subjective and objective parameters of patients in common disease conditions
- **CLO2. Assist** other healthcare providers to analyse drug related problems and provide therapeutic interventions
- CLO3. Participate in planning the rational medicine therapy for common diseases
- CLO4. Design and deliver discharge counselling for patients

СН	Торіс	Hours								
1.	Pharmacotherapeutics – Introduction, scope, and objectives. Rational									
	use of Medicines, Evidence Based Medicine, Essential Medicines List,									
	Standard Treatment Guidelines (STGs)									
2.	Definition, etiopathogenesis, clinical manifestations, non-pharmacological									
	and pharmacological management of the diseases associated with									
	(a) Cardiovascular system	8								
	• Hypertension									
	Angina and Myocardial infarction									
	Hyperlipidaemia									
	Congestive Heart Failure									
	(b) Respiratory System	4								

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	• Asthma	
	• COPD	
(c)	Endocrine System	5
	• Diabetes	
	• Thyroid disorders - Hypo and Hyperthyroidism	
(d)	Central Nervous System	8
	• Epilepsy	
	Parkinson"s disease	
	• Alzheimer"s disease	
	• Stroke	
	• Migraine	
(e)	Gastro Intestinal Disorders	8
	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	
(σ)	Infectious diseases	12
(5)	Tuberculosis	
	Pneumonia	
	Urinary tract infections	
	Hepatitis	
	 Gonorrhoea and Syphilis 	
	26.1	
	HIV and Opportunistic infections Wind Infections (SARS, CaV2)	
(h)	 Viral Infections (SARS, CoV2) Musculoskeletal disorders 	3
(11)	Rheumatoid arthritis	3
	Osteoarthritis	
(i)	Dermatology	3
(-)	• Psoriasis	_
	• Scabies	
	• Eczema	
(i)	Psychiatric Disorders	4
(J)	• Depression	-
	4	

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• Anxiety	
 Psychosis 	
(k) Ophthalmology	2
 Conjunctivitis (bacterial and viral) 	
Glaucoma	
(l) Anti-microbial Resistance	2
(m) Women's Health	4
 Polycystic Ovary Syndrome 	
 Dysmenorrhea 	
Premenstrual Syndrome	

Recommonded Books:

- 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.

ER20-24P. PHARMACOTHERAPEUTICS (Practical)

75 Hours (3 Hours/week)

Course	Course Title	Hours		ırs	Component	Exam	WT		Passing
Code		L	T	P	•				Min.(%)
ER20-	Pharmaco therapeutics	-	-	1/wk	Practical	Sessional- 1	80		
24P				25/yr	(100 marks)	Sessional- 2	80	20	40%
						Sessional- 3	80		4070
	(Practical)					EAE	80	80	

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

- **CLO1. Write** SOAP (Subjective, Objective, Assessment and Plan) notes for the given clinical cases of selected common diseases
- **CLO2.** Counsel the patients about the disease conditions, uses of drugs, methods of handling and administration of drugs, life-style modifications, and monitoring parameters.

No. Practicals

- 1. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions.
 - 1. Hypertension
 - 2. Angina Pectoris
 - 3. Myocardial Infarction
 - 4. Hyperlipidaemia
 - 5. Rheumatoid arthritis
 - 6. Asthma
 - 7. COPD

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- 8. Diabetes
- 9. Epilepsy
- 10. Stroke
- 11. Depression
- 12. Tuberculosis
- 13. Anaemia (any one type as covered in theory)
- **14**. Viral infection (any one type as covered in theory)
- 15. Dermatological conditions (any one condition as covered in theory)
- 2. Patient counselling exercises using role plays based on the real / hypothetical clinical case scenarios. The students are expected to provide counselling on disease condition, medications, life-style modifications, monitoring parameters, etc. and the same shall be documented. (Minimum 5 cases)
- 3. Simulated cases to enable dose calculation of selected drugs in paediatrics, and geriatrics under various pathological conditions. (Minimum 4 cases)

Recommonded Books:

- 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.

ER20-25T. HOSPITAL & CLINICAL PHARMACY (Theory)

75 Hours (3 Hours/week)

Course Code	Course Title	L	T	P	Component	Exam	WT		Passing Min. (%)
ER20-	Hospital &	3/wk	1/wk	-	Theory	Sessional-1	40		
25T.	Clinical	75/yr	25/yr		(100 Marks)	Sessional-2	40	20	40%
	Pharmacy					Sessional-3	40		4070
	(Theory)					EAE	80	80	

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:

- CLO1. Explain about the basic concepts of hospital pharmacy administration
- **CLO2. Manage** the supply chain and distribution of medicines within the hospital settings
- **CLO3. Assist** the other healthcare providers in monitoring drug therapy and address drug related problems
- CLO4. Interpret common lab investigation reports for optimizing drug therapy

СН		Topic	Hours
1.	Hospital Pharmacy		6

- Definition, scope, national and international scenario
- Organisational structure
- Professional responsibilities, Qualification and experience requirements, job specifications, work load requirements and inter professional relationships

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- Good Pharmacy Practice (GPP) in hospital
- Hospital Pharmacy Standards (FIP Basel Statements, AHSP)
- Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists

2. Different committees in the hospital

4

- 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

3. Supply Chain and Inventory Control

14

- Preparation of Drug lists High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics
- Procedures of Drug Purchases Drug selection, short term, long term, and tender/e-tender process, quotations, etc.
- Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc.
- Inventory Management of Central Drug Store Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold rooms)
- FEFO, FIFO methods
- Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs
- Documentation purchase and inventory

4. **Drug Distribution**

7

- Drug distribution (in- patients and out patients) Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method.
- Distribution of drugs to ICCU/ICU/NICU/Emergency wards.
- Automated drug dispensing systems and devices

5.	Compounding in hospitals. Bulk compounding, IV admixture								
•	services and incompatibilities, Total parenteral nutrition								
6.	Radiopharmaceuticals – Storage, dispensing and disposal of Radiopharmaceuticals								
7.	Application of computers in Hospital Pharmacy Practice, Electronic health records, Softwares used in hospital pharmacy								
8.	Clinical Pharmacy: Definition, scope, and development - in India and other countries								
	Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc.								
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								
	pharmaceutical care								
	Medication Therapy Management, Home Medication Review								
10.	Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results]							
	Haematological, Liver function, Renal function, thyroid function tests								
	 Tests associated with cardiac disorders 								
	Fluid and electrolyte balance								
	Pulmonary Function Tests								

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

12. Pharmacovigilance

2

6

- Definition, aim and scope
- Overview of Pharmacovigilance
- **Medication errors:** Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP

Drug Interactions: Definition, types, clinical significance of drug interactions

Recommonded Books

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

ER20-25P. HOSPITAL & CLINICAL PHARMACY (Practical)

75 Hours (3 Hours/week)

Course	Course Title	Hours		Component	Exam	WT		Passing	
Code		L	T	P					Min.(%)
ER20-	Hospital &	-	-	1/wk	Practical	Sessional- 1	80		
25P	Clinical			25/yr	(100 marks)	Sessional- 2	80	10	
	Pharmacy					Sessional- 3	80		
	(Practical)					Assignment-1	05		40%
						Assignment-2	05	05	4070
						Assignment-3	05		
						FVR	05	05	
						EAE	80	80	

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:

- **CLO1. Professionally** handle and answer the drug information queries
- **CLO2. Interpret** the common laboratory reports
- CLO3. Report suspected adverse drug reactions using standard procedures
- **CLO4. Understand** the uses and methods of handling various medical/surgical aids and devices
- **CLO5. 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.

No.	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
	i. Orthopaedic and Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc.
	 Different types of bandages such as sterile gauze, cotton, crepe bandages, etc.
	iii. 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)
	poisoning, fractures, burns, epilepsy etc.
7.	Vaccination and injection techniques (IV, IM, SC) using mannequins (5 activities)
8.	Use of Hospital Pharmacy Software and various digital health tools

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. 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.

Recommonded Books

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

ER20-26T. PHARMACY LAW & ETHICS (Theory)

75 Hours (3 Hours/week)

Course	Course Title		Hours		Component	Exam	WT		Passing
Code		L	T	P					Min. (%)
ER20-	Pharmacy Law	3/wk	1/wk	-	Theory	Sessional-1	40		
26T.	& Ethics	75/yr	25/yr		(100 Marks)	Sessional-2	40	20	40%
	(Theory)					Sessional-3	40		4070
						EAE	80	80	

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:

- CLO1. Describe the history and evolution of pharmacy law in India
- **CLO2. Interpret** the act and rules regulating the profession and practice of pharmacy in India
- **CLO3. Discuss** the various codes of ethics related to practice standards in pharmacy
- **CLO4.** Interpret the fundamentals of patent laws from the perspectives of pharmacy

СН	Topic	Hours
1.	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2.	Pharmacy Act-1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015	8
3.	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit.	23

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

Study of schedule C and C1, G, H, H1, K, P, M, N, and X.

Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy

Drugs Prohibited for manufacture and sale in India

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

- Narcotic Drugs and Psychotropic Substances Act 1985 and Rules
 Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.

 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, Definitions, CPCSEA brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records,
- 7. Poisons Act-1919:

 Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons

Power to suspend or revoke registration, Offences and Penalties.

- 8. FSSAI (Food Safety and Standards Authority of India) Act and Rules: 2
 brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements
- 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)

10.	Code of Pharmaceutical Ethics:	5
	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.	_
11.	Medical Termination of Pregnancy Act and Rules –	2
	Basic understanding, salient features, and Amendments	
12.	Role of all the government pharma regulator bodies –	1
	Central Drugs Standards Control Organization (CDSCO),	
	Indian Pharmacopoeia Commission (IPC)	
13.	Good Regulatory practices	3
15.	(documentation, licenses, renewals, e-governance) in Community	3
	Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale	
	business,	
	inspections, import, export of drugs and medical devices	
	1 , 1 , 1	
14.	Introduction to BCS system of classification,	7
	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	
15.	Blood bank – basic requirements and functions	2
16.	Clinical Establishment Act and Rules –	2
	Aspects related to Pharmacy	
17.	Biomedical Waste Management Rules 2016 –	2
	Basic aspects, and aspects related to pharma manufacture to disposal of	
	pharma / medical waste at homes, pharmacies, and hospitals	
18.	Bioethics –	2
18.	Bioethics – Basic concepts, history and principles, Brief overview of ICMR"s National	2
18.	Basic concepts, history and principles. Brief overview of ICMR"s National	2
18.		2
18.	Basic concepts, history and principles. Brief overview of ICMR"s National Ethical Guidelines for Biomedical and Health Research involving human	2
19.	Basic concepts, history and principles. Brief overview of ICMR"s National Ethical Guidelines for Biomedical and Health Research involving human participants Introduction to the Consumer Protection Act	1
19. 20.	Basic concepts, history and principles. Brief overview of ICMR"s National Ethical Guidelines for Biomedical and Health Research involving human participants Introduction to the Consumer Protection Act Introduction to the Disaster Management Act	1
19.	Basic concepts, history and principles. Brief overview of ICMR"s National Ethical Guidelines for Biomedical and Health Research involving human participants Introduction to the Consumer Protection Act	1

Recommonded Books:

- 1. Text book of Forensic Pharmacy by B.M. Mithal
- 2. Forensic Pharmacy by B. Suresh
- 3. Hand book of drug law-by M.L. Mehra
- 4. A text book of Forensic Pharmacy by N.K. Jain
- 5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
- 6. Medicinal and Toilet preparations Act 1955 by Govt. of India publications.
- 7. Narcotic Drugs and Psychotropic Substances Act by Govt. of India publications
- 8. Drugs and Magic Remedies Act by Govt. of India publications.
- 9. CDSCO Website, NPPA Website
- 10. Books on Drugs and Cosmetic Act by Nilesh Gandhi and Sudhir Deshpande
- 11. Text Book of Forensic Pharmacy by Dr Guruprasad Mohanta

Assignment

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

Facilities





Auditorium



Reading Hall



Well Equipped Classroom



Sophisticated Computer Lab



Advanced Laboratories





Food Court







Transport

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