Annexure - I

Pharmacy Council of India
New Delhi

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

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

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

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

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

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

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

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7. ER-2020 D.Pharm Syllabus – Part I

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

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PHARMACEUTICS – THEORY

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

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

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

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

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

1. Describe about the different dosage forms and their formulation aspects
2. Explain the advantages, disadvantages, and quality control tests of different dosage forms
3. Discuss the importance of quality assurance and good manufacturing practices

Chapter	Topics	Hours
1	• History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations. • Pharmacy as a career • Pharmacopoeia: Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia	7
2	**Packaging materials**: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	5
3	**Pharmaceutical aids:** Organoleptic (Colouring, flavouring, and sweetening) agents **Preservatives:** Definition, types with examples and uses	3
4	**Unit operations:** Definition, objectives/applications, principles, construction, and workings of:	9
	Size reduction: hammer mill and ball mill	
	Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves	

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	Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer	
	Filtration: Theory of filtration, membrane filter and sintered glass filter	
	Drying: working of fluidized bed dryer and process of freeze drying	
	Extraction: Definition, Classification, method, and applications	
5	**Tablets** – coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi-layered, etc.)	**8**
	Capsules - hard and soft gelatine capsules	**4**
	Liquid oral preparations - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution	**6**
	Topical preparations - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries	**8**
	Nasal preparations, Ear preparations	**2**
	Powders and granules - Insufflations, dusting powders, effervescent powders, and effervescent granules	**3**
	Sterile formulations – Injectables, eye drops and eye ointments	**6**
	Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.	**4**
6	**Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants** **Quality control and quality assurance**: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation	**5**
7	**Novel drug delivery systems:** Introduction, Classification with examples, advantages, and challenges	**5**

PHARMACEUTICS – PRACTICAL

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

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

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

1. Calculation of working formula from the official master formula

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2. Formulation of dosage forms based on working formula
3. Appropriate Packaging and labelling requirements
4. Methods of basic quality control tests

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

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

Practicals

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

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

4. Demonstration on various stages of tablet manufacturing processes

5. Appropriate methods of usage and storage of all dosage forms including special dosage such as different types of inhalers, spacers, insulin pens
6. Demonstration of quality control tests and evaluation of common dosage forms viz. tablets, capsules, emulsion, sterile injections as per the monographs

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Assignments

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

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

Field Visit

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

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PHARMACEUTICAL CHEMISTRY – THEORY

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

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

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

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

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

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

Chapter	Topic	Hours
1	**Introduction to Pharmaceutical chemistry:** Scope and objectives **Sources and types of errors:** Accuracy, precision, significant figures **Impurities in Pharmaceuticals**: Source and effect of impurities in Pharmacopoeial substances, importance of limit test, Principle and procedures of Limit tests for chlorides, sulphates, iron, heavy metals and arsenic.	8
2	**Volumetric analysis**: Fundamentals of volumetric analysis, Acid-base titration, non-aqueous titration, precipitation titration, complexometric titration, redox titration **Gravimetric analysis:** Principle and method.	8

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3	**Inorganic Pharmaceuticals**: Pharmaceutical formulations, market preparations, storage conditions and uses of • **Haematinics:** Ferrous sulphate, Ferrous fumarate, Ferric ammonium citrate, Ferrous ascorbate, Carbonyl iron • **Gastro-intestinal Agents:** Antacids :Aluminium hydroxide gel, Magnesium hydroxide, Magaldrate, Sodium bicarbonate, Calcium Carbonate, Acidifying agents, Adsorbents, Protectives, Cathartics • **Topical agents:** Silver Nitrate, Ionic Silver, Chlorhexidine Gluconate, Hydrogen peroxide, Boric acid, Bleaching powder, Potassium permanganate • **Dental products:** Calcium carbonate, Sodium fluoride, Denture cleaners, Denture adhesives, Mouth washes • **Medicinal gases:** Carbon dioxide, nitrous oxide, oxygen	**7**
4	Introduction to nomenclature of organic chemical systems with particular reference to heterocyclic compounds containing up to Three rings	**2**
Study of the following category of medicinal compounds with respect to classification, chemical name, chemical structure (compounds marked with*) uses, stability and storage conditions, different types of formulations and their popular brand names		
5	**Drugs Acting on Central Nervous System** • **Anaesthetics:** Thiopental Sodium*, Ketamine Hydrochloride*, Propofol • **Sedatives and Hypnotics:** Diazepam*, Alprazolam*, Nitrazepam, Phenobarbital* • **Antipsychotics:** Chlorpromazine Hydrochloride*, Haloperidol*, Risperidone*, Sulpiride*, Olanzapine, Quetiapine, Lurasidone • **Anticonvulsants:** Phenytoin*, Carbamazepine*, Clonazepam, Valproic Acid*, Gabapentin*, Topiramate, Vigabatrin, Lamotrigine • **Anti-Depressants:** Amitriptyline Hydrochloride*, Imipramine Hydrochloride*, Fluoxetine*, Venlafaxine, Duloxetine, Sertraline, Citalopram, Escitalopram, Fluvoxamine, Paroxetine	**9**
6	**Drugs Acting on Autonomic Nervous System** • **Sympathomimetic Agents: *Direct Acting:*** Nor-Epinephrine*, Epinephrine, Phenylephrine,	**9**

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	Dopamine*, Terbutaline, Salbutamol (Albuterol), Naphazoline*, Tetrahydrozoline. ***Indirect Acting Agents:*** Hydroxy Amphetamine, Pseudoephedrine. Agents With Mixed Mechanism**:** Ephedrine, Metaraminol • **Adrenergic Antagonists:** Alpha Adrenergic Blockers: Tolazoline, Phentolamine • Phenoxybenzamine, Prazosin. Beta Adrenergic Blockers: Propranolol*, Atenolol*, Carvedilol • **Cholinergic Drugs and Related Agents:** Direct Acting Agents: Acetylcholine*, Carbachol, And Pilocarpine. Cholinesterase Inhibitors: Neostigmine*, Edrophonium Chloride, Tacrine Hydrochloride, Pralidoxime Chloride, Echothiopate Iodide • **Cholinergic Blocking Agents:** Atropine Sulphate*, Ipratropium Bromide ***Synthetic Cholinergic Blocking Agents***: Tropicamide, Cyclopentolate Hydrochloride, Clidinium Bromide, Dicyclomine Hydrochloride*	
7	**Drugs Acting on Cardiovascular System** • **Anti-Arrhythmic Drugs**: Quinidine Sulphate, Procainamide Hydrochloride, Verapamil, Phenytoin Sodium*, Lidocaine Hydrochloride, Lorcainide Hydrochloride, Amiodarone and Sotalol • **Anti-Hypertensive Agents**: Propranolol*, Captopril*, Ramipril, Methyldopate Hydrochloride, Clonidine Hydrochloride, Hydralazine Hydrochloride, Nifedipine, • **Antianginal Agents**: Isosorbide Dinitrate	**5**
8	**Diuretics:** Acetazolamide, Frusemide*, Bumetanide, Chlorthalidone, Benzthiazide, Metolazone, Xipamide, Spironolactone	**2**
9	**Hypoglycemic Agents:** Insulin and Its Preparations, Metformin*, Glibenclamide*, Glimepiride, Pioglitazone, Repaglinide, Gliflozins, Gliptins	**3**
10	**Analgesic And Anti-Inflammatory Agents:** Morphine Analogues, Narcotic Antagonists; ***Nonsteroidal Anti-Inflammatory Agents (NSAIDs)*** - Aspirin*, Diclofenac, Ibuprofen*, Piroxicam, Celecoxib, Mefenamic Acid, Paracetamol*, Aceclofenac	**3**
11	**Anti-Infective Agents** • **Antifungal Agents:** Amphotericin-B, Griseofulvin, Miconazole, Ketoconazole*, Itraconazole, Fluconazole*, Naftifine Hydrochloride	**8**

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	• **Urinary Tract Anti-Infective Agents:** Norfloxacin, Ciprofloxacin, Ofloxacin*, Moxifloxacin, • **Anti-Tubercular Agents:** INH*, Ethambutol, Para Amino Salicylic Acid, Pyrazinamide, Rifampicin, Bedaquiline, Delamanid, Pretomanid* • **Antiviral Agents:** Amantadine Hydrochloride, Idoxuridine, Acyclovir*, Foscarnet, Zidovudine, Ribavirin, Remdesivir, Favipiravir • **Antimalarials:** Quinine Sulphate, Chloroquine Phosphate*, Primaquine Phosphate, Mefloquine*, Cycloguanil, Pyrimethamine, Artemisinin • **Sulfonamides:** Sulfanilamide, Sulfadiazine, Sulfametho xazole, Sulfacetamide*, Mafenide Acetate, Cotrimoxazole, Dapsone*	
12	**Antibiotics:** Penicillin G, Amoxicillin*, Cloxacillin, Streptomycin, ***Tetracyclines:*** Doxycycline, Minocycline, ***Macrolides:*** Erythromycin, Azithromycin, ***Miscellaneous:*** Chloramphenicol* Clindamycin	**8**
13	**Anti-Neoplastic Agents:** Cyclophosphamide*, Busulfan, Mercaptopurine, Fluorouracil*, Methotrexate, Dactinomycin, Doxorubicin Hydrochloride, Vinblastine Sulphate, Cisplatin*, Dromostanolone Propionate	**3**

PHARMACEUTICAL CHEMISTRY – PRACTICAL

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

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

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

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

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

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

Practicals

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

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Assignments

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

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

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PHARMACOGNOSY – THEORY

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

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

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

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

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

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

Chapter	Topic	Hours
1	Definition, history, present status and scope of Pharmacognosy	2
2	**Classification of drugs:** • Alphabetical • Taxonomical • Morphological • Pharmacological • Chemical • Chemo-taxonomical	4
3	**Quality control of crude drugs:** • Different methods of adulteration of crude drugs • Evaluation of crude drugs	6

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<table>
<tr><td>4</td><td colspan="2">Brief outline of occurrence, distribution, isolation, identification tests, therapeutic activity and pharmaceutical applications of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.</td><td>6</td></tr>
<tr><td>5</td><td colspan="2">Biological source, chemical constituents and therapeutic efficacy of the following categories of crude drugs.
<table>
<tr><td>Laxatives</td><td>Aloe, Castor oil, Ispaghula, Senna</td></tr>
<tr><td>Cardiotonic</td><td>Digitalis, Arjuna</td></tr>
<tr><td>Carminatives and G.I. regulators</td><td>Coriander, Fennel, Cardamom, Ginger, Clove, Black Pepper, Asafoetida, Nutmeg, Cinnamon</td></tr>
<tr><td>Astringents</td><td>Myrobalan, Black Catechu, Pale Catechu</td></tr>
<tr><td>Drugs acting on nervous system</td><td>Hyoscyamus, Belladonna, Ephedra, Opium, Tea leaves, Coffee seeds, Coca</td></tr>
<tr><td>Anti-hypertensive</td><td>Rauwolfia</td></tr>
<tr><td>Anti-tussive</td><td>Vasaka, Tolu Balsam</td></tr>
<tr><td>Anti-rheumatics</td><td>Colchicum seed</td></tr>
<tr><td>Anti-tumour</td><td>Vinca, Podophyllum</td></tr>
<tr><td>Antidiabetics</td><td>Pterocarpus, Gymnema</td></tr>
<tr><td>Diuretics</td><td>Gokhru, Punarnava</td></tr>
<tr><td>Anti-dysenteric</td><td>Ipecacuanha</td></tr>
<tr><td>Antiseptics and disinfectants</td><td>Benzoin, Myrrh, Neem, Turmeric</td></tr>
<tr><td>Antimalarials</td><td>Cinchona, Artemisia</td></tr>
<tr><td>Oxytocic</td><td>Ergot</td></tr>
<tr><td>Vitamins</td><td>Cod liver oil, Shark liver oil</td></tr>
<tr><td>Enzymes</td><td>Papaya, Diastase, Pancreatin, Yeast</td></tr>
<tr><td>Pharmaceutical Aids</td><td>Kaolin, Lanolin, Beeswax, Acacia, Tragacanth, Sodium alginate, Agar, Guar gum, Gelatine</td></tr>
<tr><td>Miscellaneous</td><td>Squill, Galls, Ashwagandha, Tulsi, Guggul</td></tr>
</table></td><td>30</td></tr>
<tr><td>6</td><td colspan="2">Plant fibres used as surgical dressings: Cotton, silk, wool and regenerated fibres
Sutures – Surgical Catgut and Ligatures</td><td>3</td></tr>
<tr><td>7</td><td colspan="2">• Basic principles involved in the traditional systems of medicine like: Ayurveda, Siddha, Unani and Homeopathy

• Method of preparation of Ayurvedic formulations like: Arista, Asava, Gutika, Taila, Churna, Lehya and Bhasma</td><td>8</td></tr>
</table>

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8	Role of medicinal and aromatic plants in national economy and their export potential	**2**
9	**Herbs as health food:** Brief introduction and therapeutic applications of: Nutraceuticals, Antioxidants, Pro-biotics, Pre-biotics, Dietary fibres, Omega-3-fatty acids, Spirulina, Carotenoids, Soya and Garlic	**4**
10	Introduction to herbal formulations	**4**
11	**Herbal cosmetics:** Sources, chemical constituents, commercial preparations, therapeutic and cosmetic uses of: Aloe vera gel, Almond oil, Lavender oil, Olive oil, Rosemary oil, Sandal Wood oil	**4**
12	Phytochemical investigation of drugs	**2**

PHARMACOGNOSY – PRACTICAL

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

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

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

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

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

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

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Practicals

1. Morphological Identification of the following drugs:
Ispaghula, Senna, Coriander, Fennel, Cardamom, Ginger, Nutmeg, Black Pepper, Cinnamon, Clove, Ephedra, Rauwolfia, Gokhru, Punarnava, Cinchona, Agar.

2. Gross anatomical studies (Transverse Section) of the following drugs:
Ajwain, Datura, Cinnamon, Cinchona, Coriander, Ashwagandha, Liquorice, Clove, Curcuma, Nux vomica, Vasaka

3. Physical and chemical tests for evaluation of any FIVE of the following drugs:
Asafoetida, Benzoin, Pale catechu, Black catechu, Castor oil, Acacia, Tragacanth, Agar, Guar gum, Gelatine.

Assignments

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

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

Field Visit

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

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HUMAN ANATOMY AND PHYSIOLOGY – THEORY

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

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

Course Objectives: This course will discuss the following:

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

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

1. Describe the various organ systems of the human body
2. Discuss the anatomical features of the important human organs and tissues
3. Explain the homeostatic mechanisms regulating the normal physiology in the human system
4. Discuss the significance of various vital physiological parameters of the human body

Chapter	Topic	Hours
1	Scope of Anatomy and Physiology Definition of various terminologies	2
2	**Structure of Cell**: Components and its functions	2
3	**Tissues of the human body**: Epithelial, Connective, Muscular and Nervous tissues – their sub-types and characteristics.	4
4	**Osseous system**: structure and functions of bones of axial and appendicular skeleton Classification, types and movements of joints, disorders of joints	3 3
5	**Haemopoietic system** ● Composition and functions of blood ● Process of Hemopoiesis ● Characteristics and functions of RBCs, WBCs, and platelets ● Mechanism of Blood Clotting ● Importance of Blood groups	8

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6	**Lymphatic system** ● Lymph and lymphatic system, composition, function and its formation. ● Structure and functions of spleen and lymph node.	**3**
7	**Cardiovascular system** ● Anatomy and Physiology of heart ● Blood vessels and circulation (Pulmonary, coronary and systemic circulation) ● Cardiac cycle and Heart sounds, Basics of ECG ● Blood pressure and its regulation	**8**
8	**Respiratory system** ● Anatomy of respiratory organs and their functions. ● Regulation, and Mechanism of respiration. ● Respiratory volumes and capacities – definitions	**4**
9	**Digestive system** ● Anatomy and Physiology of the GIT ● Anatomy and functions of accessory glands ● Physiology of digestion and absorption	**8**
10	**Skeletal muscles** ● Histology ● Physiology of muscle contraction ● Disorder of skeletal muscles	**2**
11	**Nervous system** ● Classification of nervous system ● Anatomy and physiology of cerebrum, cerebellum, mid brain ● Function of hypothalamus, medulla oblongata and basal ganglia ● Spinal cord-structure and reflexes ● Names and functions of cranial nerves. ● Anatomy and physiology of sympathetic and parasympathetic nervous system (ANS)	**8**
12	**Sense organs - Anatomy and physiology of** ● Eye ● Ear ● Skin ● Tongue ● Nose	**6**
13	**Urinary system** ● Anatomy and physiology of urinary system ● Physiology of urine formation ● Renin - angiotensin system ● Clearance tests and micturition	**4**

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14	**Endocrine system (Hormones and their functions)** ● Pituitary gland ● Adrenal gland ● Thyroid and parathyroid gland ● Pancreas and gonads	**6**
15	**Reproductive system** ● Anatomy of male and female reproductive system ● Physiology of menstruation ● Spermatogenesis and Oogenesis ● Pregnancy and parturition	**4**

HUMAN ANATOMY AND PHYSIOLOGY – PRACTICAL

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

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

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

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

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

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

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Practicals

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

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SOCIAL PHARMACY – THEORY

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

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

Course Objectives: This course will discuss about basic concepts of

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

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

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

Chapter	Topic	Hours
1	**Introduction to Social Pharmacy** • Definition and Scope. Social Pharmacy as a discipline and its scope in improving the public health. Role of Pharmacists in Public Health. (2) • Concept of Health -WHO Definition, various dimensions, determinants, and health indicators. (3) • National Health Policy – Indian perspective (1) • Public and Private Health System in India, National Health Mission (2) • Introduction to Millennium Development Goals, Sustainable Development Goals, FIP Development Goals (1)	9
2	**Preventive healthcare – Role of Pharmacists in the following** • Demography and Family Planning (3) • Mother and child health, importance of breastfeeding, ill effects of infant milk substitutes and bottle feeding (2) • Overview of Vaccines, types of immunity and immunization (4)	18

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	• Effect of Environment on Health – Water pollution, importance of safe drinking water, waterborne diseases, air pollution, noise pollution, sewage and solid waste disposal, occupational illnesses, Environmental pollution due to pharmaceuticals (7) • Psychosocial Pharmacy: Drugs of misuse and abuse – psychotropics, narcotics, alcohol, tobacco products. Social Impact of these habits on social health and productivity and suicidal behaviours (2)	
3	**Nutrition and Health** • Basics of nutrition – Macronutrients and Micronutrients (3) • Importance of water and fibres in diet (1) • Balanced diet, Malnutrition, nutrition deficiency diseases, ill effects of junk foods, calorific and nutritive values of various foods, fortification of food (3) • Introduction to food safety, adulteration of foods, effects of artificial ripening, use of pesticides, genetically modified foods (1) • Dietary supplements, nutraceuticals, food supplements – indications, benefits, Drug-Food Interactions (2)	**10**
4	Introduction to Microbiology and common microorganisms (3) **Epidemiology:** Introduction to epidemiology, and its applications. Understanding of terms such as epidemic, pandemic, endemic, mode of transmission, outbreak, quarantine, isolation, incubation period, contact tracing, morbidity, mortality, . (2) Causative agents, epidemiology and clinical presentations and Role of Pharmacists in educating the public in prevention of the following communicable diseases: • Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1, SARS, MERS, COVID-19), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis, Ebola (7) • Intestinal infections – poliomyelitis, viral hepatitis, cholera, acute diarrheal diseases, typhoid, amebiasis, worm infestations, food poisoning (7)	**28**

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	• Arthropod-borne infections - dengue, malaria, filariasis and, chikungunya (4) • Surface infections – trachoma, tetanus, leprosy (2) • STDs, HIV/AIDS (3)	
5	Introduction to health systems and **all ongoing National Health programs** in India, their objectives, functioning, outcome, and the role of pharmacists.	**8**
6	**Pharmacoeconomics** – Introduction, basic terminologies, importance of pharmacoeconomics	**2**

SOCIAL PHARMACY – PRACTICAL

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

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

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

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

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

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

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

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Practicals

1. National immunization schedule for children, adult vaccine schedule, Vaccines which are not included in the National Immunization Program.
2. RCH – reproductive and child health – nutritional aspects, relevant national health programmes.
3. Family planning devices
4. Microscopical observation of different microbes (readymade slides)
5. Oral Health and Hygiene
6. Personal hygiene and etiquettes – hand washing techniques, Cough and sneeze etiquettes.
7. Various types of masks, PPE gear, wearing/using them, and disposal.
8. Menstrual hygiene, products used
9. First Aid – Theory, basics, demonstration, hands on training, audio-visuals, and practice, BSL (Basic Life Support) Systems [SCA - Sudden Cardiac Arrest, FBAO - Foreign Body Airway Obstruction, CPR, Defibrillation (using AED) (Includes CPR techniques, First Responder).
10. Emergency treatment for all medical emergency cases viz. snake bite, dog bite, insecticide poisoning, fractures, burns, epilepsy etc.
11. Role of Pharmacist in Disaster Management.
12. Marketed preparations of disinfectants, antiseptics, fumigating agents, antilarval agents, mosquito repellents, etc.
13. Health Communication: Audio / Video podcasts, Images, Power Point Slides, Short Films, etc. in regional language(s) for mass communication / education / Awareness on 5 different communicable diseases, their signs and symptoms, and prevention.
14. Water purification techniques, use of water testing kit, calculation of Content/percentage of $KMnO_4$, bleaching powder to be used for wells/tanks
15. Counselling children on junk foods, balanced diets – using Information, Education and Communication (IEC), counselling, etc. (Simulation Experiments).
16. Preparation of various charts on nutrition, sources of various nutrients from Locally available foods, calculation of caloric needs of different groups (e.g. child, mother, sedentary lifestyle, etc.). Chart of glycemic index of foods.
17. Tobacco cessation, counselling, identifying various tobacco containing products through charts/pictures

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Assignment

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

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

Field Visits

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

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

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8. ER-2020 D.Pharm Syllabus – Part II

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

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PHARMACOLOGY – THEORY

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

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

Course Objectives: This course will discuss the following:

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

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

1. Describe the basic concepts of pharmacokinetics and pharmacodynamics2. Enlist the various classes and drugs of choices for any given disease condition
3. Advice the dosage regimen, route of administration and contraindications for a given drug
4. Describe the common adverse drug reactions

Chapter	Topic	Hours
1	**General Pharmacology** • Introduction and scope of Pharmacology • Various routes of drug administration - advantages and disadvantages • Drug absorption - definition, types, factors affecting drug absorption • Bioavailability and the factors affecting bioavailability • Drug distribution - definition, factors affecting drug distribution • Biotransformation of drugs - Definition, types of biotransformation reactions, factors influencing drug metabolisms • Excretion of drugs - Definition, routes of drug excretion • General mechanisms of drug action and factors modifying drug action	**10**

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2	**Drugs Acting on the Peripheral Nervous System** • Steps involved in neurohumoral transmission • Definition, classification, pharmacological actions, dose, indications, and contraindications of a) Cholinergic drugs b) Anti-Cholinergic drugs c) Adrenergic drugs d) Anti-adrenergic drugs e) Neuromuscular blocking agents f) Drugs used in Myasthenia gravis g) Local anaesthetic agents h) Non-Steroidal Anti-Inflammatory drugs (NSAIDs)	**11**
3	**Drugs Acting on the Eye** Definition, classification, pharmacological actions, dose, indications and contraindications of • Miotics • Mydriatics • Drugs used in Glaucoma	**2**
4	**Drugs Acting on the Central Nervous System** Definition, classification, pharmacological actions, dose, indications, and contraindications of • General anaesthetics • Hypnotics and sedatives • Anti-Convulsant drugs • Anti-anxiety drugs • Anti-depressant drugs • Anti-psychotics • Nootropic agents • Centrally acting muscle relaxants • Opioid analgesics	**8**
5	**Drugs Acting on the Cardiovascular System** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Anti-hypertensive drugs • Anti-anginal drugs • Anti-arrhythmic drugs • Drugs used in atherosclerosis and • Congestive heart failure • Drug therapy for shock	**6**

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6	**Drugs Acting on Blood and Blood Forming Organs** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Hematinic agents • Anti-coagulants • Anti-platelet agents • Thrombolytic drugs	**4**
7	Definition, classification, pharmacological actions, dose, indications, and contraindications of • Bronchodilators • Expectorants • Anti-tussive agents • Mucolytic agents	**2**
8	**Drugs Acting on the Gastro Intestinal Tract** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Anti-ulcer drugs • Anti-emetics • Laxatives and purgatives • Anti-diarrheal drugs	**5**
9	**Drugs Acting on the Kidney** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Diuretics • Anti-Diuretics	**2**
10	**Hormones and Hormone Antagonists** Physiological and pathological role and clinical uses of • Thyroid hormones • Anti-thyroid drugs • Parathormone • Calcitonin • Vitamin D • Insulin • Oral hypoglycemic agents • Estrogen • Progesterone • Oxytocin • Corticosteroids	**8**

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11	**Autocoids** • Physiological role of Histamine, 5 HT and Prostaglandins • Classification, clinical uses, and adverse effects of antihistamines and 5 HT antagonists	**3**
12	**Chemotherapeutic Agents:** Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication and contraindications of drugs belonging to following classes: • Penicillins • Cephalosporins • Aminoglycosides • Fluoroquinolones • Macrolides • Tetracyclines • Sulphonamides • Anti-tubercular drugs • Anti-fungal drugs • Anti-viral drugs • Anti-amoebic agents • Anthelmintics • Anti-malarial agents • Anti-neoplastic agents	**12**
13	**Biologicals** Definition, types, and indications of biological agents with examples	**2**

PHARMACOLOGY – PRACTICAL

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

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

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

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

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

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

Practicals

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

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

Experiments

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

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

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Assignments

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

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

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COMMUNITY PHARMACY AND MANAGEMENT – THEORY

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

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

Course Objectives: This course will discuss the following:

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

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

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

Chapter	Topic	Hours
1	**Community Pharmacy Practice** – Definition, history and development of community pharmacy - International and Indian scenarios	2
2	Professional responsibilities of community pharmacists Introduction to the concept of Good Pharmacy Practice and SOPs.	3
3	**Prescription and prescription handling** • Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage • Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them	7

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4	**Communication skills** • Definition, types of communication skills • Interactions with professionals and patients • Verbal communication skills (one-to-one, over the telephone) • Written communication skills • Body language • Patient interview techniques	**6**
5	**Patient counselling** • Definition and benefits of patient counselling • **Stages of patient counselling** - Introduction, counselling content, counselling process, and closing the counselling session • **Barriers to effective counseling** - Types and strategies to overcome the barriers • **Patient counselling points for chronic diseases/disorders** - Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS • **Patient Package Inserts** - Definition, importance and benefits, Scenarios of PPI use in India and other countries • **Patient Information leaflets** - Definition and uses	**10**
6	**Medication Adherence** Definition, factors influencing non-adherence, strategies to overcome non-adherence	**2**
7	**Health Screening Services in Community Pharmacy** Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases	**5**
9	**Over The Counter (OTC) Medications** • Definition, need and role of Pharmacists in OTC medication dispensing • OTC medications in India, counseling for OTC products • Self-medication and role of pharmacists in promoting the safe practices during self-medication • Responding to symptoms, minor ailments, and advice for self-care in conditions such as - Pain management, Cough, Cold, Diarrhea, Constipation, Vomiting, Fever, Sore throat, Skin disorders, Oral health (mouth ulcers, dental pain, gum swelling)	**15**

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

COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

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

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

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

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

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

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

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Practicals

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

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

   Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement
5. Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease)

   Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
6. Providing counselling to simulated patients for the following minor ailments (any three)

   Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
7. Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
8. Use of Community Pharmacy Software and digital health tools

Assignments

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

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

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2. List out the various abbreviations, short forms used in prescriptions and their interpretation
3. Patient Information Leaflet for a given chronic disease / disorder
4. Patient Information Leaflet for prescription / non-prescription medicines
5. Preparation of window / shelf display materials for the model community pharmacy
6. Overview of Software available for retail pharmacy management including billing, inventory, etc.
7. Dosage / Medication Reminder Aids
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.

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BIOCHEMISTRY & CLINICAL PATHOLOGY – THEORY

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

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

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

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

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

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

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

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3	**Proteins** • Definition, classification of proteins based on composition and solubility with examples • Definition, classification of amino acids based on chemical nature and nutritional requirements with examples • Structure of proteins (four levels of organization of protein structure) • Qualitative tests and biological role of proteins and amino acids • Diseases related to malnutrition of proteins.	**5**
4	**Lipids** • Definition, classification with examples • Structure and properties of triglycerides (oils and fats) • Fatty acid classification - Based on chemical and nutritional requirements with examples • Structure and functions of cholesterol in the body • Lipoproteins - types, composition and functions in the body • Qualitative tests and functions of lipids	**5**
5	**Nucleic acids** • Definition, purine and pyrimidine bases • Components of nucleosides and nucleotides with examples • Structure of DNA (Watson and Crick model), RNA and their functions	**4**
6	**Enzymes** • Definition, properties and IUB and MB classification • Factors affecting enzyme activity • Mechanism of action of enzymes, Enzyme inhibitors • Therapeutic and pharmaceutical importance of enzymes	**5**
7	**Vitamins** • Definition and classification with examples • Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins	**6**
8	**Metabolism** (Study of cycle/pathways without chemical structures) • Metabolism of Carbohydrates: Glycolysis, TCA cycle and glycogen metabolism, regulation of blood glucose	**20**

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	level. Diseases related to abnormal metabolism of Carbohydrates • Metabolism of lipids: Lipolysis, β-oxidation of Fatty acid (Palmitic acid) ketogenesis and ketolysis. Diseases related to abnormal metabolism of lipids such as Ketoacidosis, Fatty liver, Hypercholesterolemia • Metabolism of Amino acids (Proteins): General reactions of amino acids and its significance– Transamination, deamination, Urea cycle and decarboxylation. Diseases related to abnormal metabolism of amino acids, Disorders of ammonia metabolism, phenylketonuria, alkaptonuria and Jaundice. • Biological oxidation: Electron transport chain and Oxidative phosphorylation	
9	**Minerals**: Types, Functions, Deficiency diseases, recommended dietary requirements	**05**
10	**Water and Electrolytes** • Distribution, functions of water in the body • Water turnover and balance • Electrolyte composition of the body fluids, Dietary intake of electrolyte and Electrolyte balance • Dehydration, causes of dehydration and oral rehydration therapy	**05**
11	Introduction to Biotechnology	**01**
12	**Organ function tests** • Functions of kidney and routinely performed tests to assess the functions of kidney and their clinical significances • Functions of liver and routinely performed tests to assess the functions of liver and their clinical significances • Lipid profile tests and its clinical significances	**06**
13	**Introduction to Pathology of Blood and Urine** • Lymphocytes and Platelets, their role in health and disease • Erythrocytes - Abnormal cells and their significance • Normal and Abnormal constituents of Urine and their significance	**06**

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BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

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

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

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

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

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

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

Practicals

1. Qualitative analysis of carbohydrates (4 experiments)
2. Qualitative analysis of Proteins and amino acids (4 experiments)
3. Qualitative analysis of lipids (2 experiments)
4. Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
5. Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)

6. Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
7. Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

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

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PHARMACOTHERAPEUTICS - THEORY

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

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

Course Objectives: This course will discuss about

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

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

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

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

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	• Parkinson's disease • Alzheimer's disease • Stroke • Migraine	
	(e) Gastro Intestinal Disorders • Gastro oesophageal reflux disease • Peptic Ulcer Disease • Alcoholic liver disease • Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis)	**8**
	(f) Haematological disorders • Iron deficiency anaemia • Megaloblastic anaemia	**4**
	(g) Infectious diseases • Tuberculosis • Pneumonia • Urinary tract infections • Hepatitis • Gonorrhoea and Syphilis • Malaria • HIV and Opportunistic infections • Viral Infections (SARS, CoV2)	**12**
	(h) Musculoskeletal disorders • Rheumatoid arthritis • Osteoarthritis	**3**
	(i) Dermatology • Psoriasis • Scabies • Eczema	**3**
	(j) Psychiatric Disorders • Depression • Anxiety • Psychosis	**4**
	(k) Ophthalmology • Conjunctivitis (bacterial and viral) • Glaucoma	**2**
	(l) Anti-microbial Resistance	**2**
	(m) Women's Health • Polycystic Ovary Syndrome • Dysmenorrhea • Premenstrual Syndrome	**4**

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PHARMACOTHERAPEUTICS – PRACTICAL

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

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

Course Objectives: This course will train the students on

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

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

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

Practicals

I. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions.

1. Hypertension
2. Angina Pectoris
3. Myocardial Infarction
4. Hyperlipidaemia
5. Rheumatoid arthritis
6. Asthma
7. COPD
8. Diabetes
9. Epilepsy
10. Stroke
11. Depression
12. Tuberculosis
13. Anaemia (any one type as covered in theory)
14. Viral infection (any one type as covered in theory)
15. Dermatological conditions (any one condition as covered in theory)

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

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

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HOSPITAL AND CLINICAL PHARMACY – THEORY

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

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

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

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

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

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

S. No.	Topic	Hours
1	**Hospital Pharmacy** • Definition, scope, national and international scenario • Organisational structure • Professional responsibilities, Qualification and experience requirements, job specifications, work–load requirements and inter professional relationships • Good Pharmacy Practice (GPP) in hospital • Hospital Pharmacy Standards (FIP Basel Statements, AHSP) • Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists	6
2	**Different Committees in the Hospital** • Pharmacy and Therapeutics Committee - Objectives, Composition, and functions • Hospital Formulary - Definition, procedure for development and use of hospital formulary	4

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	• Infection Control Committee – Role of Pharmacist in preventing Antimicrobial Resistance	
4	**Supply Chain and Inventory Control** • Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics • Procedures of Drug Purchases – Drug selection, short term, long term, and tender/e-tender process, quotations, etc. • Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc. • Inventory Management of Central Drug Store – Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold rooms) • FEFO, FIFO methods • Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs • Documentation - purchase and inventory	**14**
5	**Drug distribution** • Drug distribution (in- patients and out - patients) – Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method. • Distribution of drugs to ICCU/ICU/NICU/Emergency wards. • Automated drug dispensing systems and devices • Distribution of Narcotic and Psychotropic substances and their storage	**7**
6	Compounding in Hospitals. Bulk compounding, IV admixture services and incompatibilities, Total parenteral nutrition	**4**
7	**Radio Pharmaceuticals -** Storage, dispensing and disposal of radiopharmaceuticals	**2**
8	Application of computers in Hospital Pharmacy Practice, Electronic health records, Softwares used in hospital pharmacy	**2**
9	**Clinical Pharmacy:** Definition, scope, and development - in India and other countries Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc.	**12**

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	Daily activities of clinical pharmacists: Definition, goal, and procedure of • Ward round participation • Treatment Chart Review • Adverse drug reaction monitoring • Drug information and poisons information • Medication history • Patient counselling • Interprofessional collaboration **Pharmaceutical care**: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care **Medication Therapy Management, Home Medication Review**	
10	**Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results** • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Pulmonary Function Tests	**10**
11	**Poisoning**: Types of poisoning: Clinical manifestations and Antidotes **Drugs and Poison Information Centre and their services** – Definition, Requirements, Information resources with examples, and their advantages and disadvantages	**6**
12	**Pharmacovigilance** • Definition, aim and scope • Overview of Pharmacovigilance	**2**
13	**Medication errors**: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP **Drug Interactions:** Definition, types, clinical significance of drug interactions	**6**

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HOSPITAL AND CLINICAL PHARMACY – PRACTICAL

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

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

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

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

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

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

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

Practicals

1. Systematic approach to drug information queries using primary / secondary / tertiary resources of information (2 cases)
2. Interpretation of laboratory reports to optimize the drug therapy in a given clinical case (2 cases)
3. Filling up IPC's ADR Reporting Form and perform causality assessments using various scales (2 cases)
4. Demonstration / simulated / hands-on experience on the identification, types, use / application /administration of
    - Orthopaedic and Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc.

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- Different types of bandages such as sterile gauze, cotton, crepe bandages, etc.
- Needles, syringes, catheters, IV set, urine bag, RYLE's tube, urine pots, colostomy bags, oxygen masks, etc.

5. Case studies on drug-drug interactions (any 2 cases)
6. Wound dressing (simulated cases and role play –minimum 2 cases)
7. Vaccination and injection techniques (IV, IM, SC) using mannequins (5 activities)
8. Use of Hospital Pharmacy Software and various digital health tools

Assignments

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

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

Field Visit

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

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PHARMACY LAW AND ETHICS – THEORY

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

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

Course Objectives: This course will discuss the following

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

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

1. Describe the history and evolution of pharmacy law in India
2. Interpret the act and rules regulating the profession and practice of pharmacy in India
3. Discuss the various codes of ethics related to practice standards in pharmacy
4. Interpret the fundamentals of patent laws from the perspectives of pharmacy

Chapter	Topics	Hours
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2	**Pharmacy Act-1948 and Rules:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. **Pharmacy Practice Regulations 2015**	5
3	**Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments** Objectives, Definitions, Legal definitions of schedules to the Act and Rules **Import of drugs** – Classes of drugs and cosmetics prohibited from import, Import under license or permit.	23

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	Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Study of schedule C and C1, G, H, H1, K, P, M, N, and X. ***Sale of Drugs*** – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India ***Administration of the Act and Rules*** – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.	
4	**Narcotic Drugs and Psychotropic Substances Act 1985 and Rules** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	**2**
5	**Drugs and Magic Remedies (Objectionable Advertisements) Act 1954** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	**2**
6	**Prevention of Cruelty to Animals Act-1960**: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	**2**
7	**Poisons Act-1919**: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	**2**
8	**FSSAI (Food Safety and Standards Authority of India) Act and Rules**: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	**2**

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

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Assignments

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

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements
2. Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
3. Licenses required, application processes (online/offline), drug regulatory office website of the respective state
4. Case studies – actions taken on violation of any act / rule related to pharmacy
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Overview of Pharma marketing practices
9. Generic Medicines

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9. Appendices

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

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Appendix – 1

A typical format for the assessment of an Assignment

Name of the College:

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

Directions: For **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.

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Appendix – 2

A typical format for the assessment of a Field Visit Report

Name of the College:

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

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

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Appendix – 3

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

As per ER 2020 regulation;

At least four laboratories specified below should be provided for:

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

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

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

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

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

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

1. Physiology, Pharmacology and Pharmacognosy Lab.

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

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

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

2. Pharmaceutical Chemistry/ Biochemistry, Clinical Pathology

S. No.	Name	Minimum required Nos. for DPharm 60 intake
1	Hot plates	5
2	Hot Air Oven	1
3	Refrigerator	1
4	Analytical Balances for demonstration	1
5	Digital balance 10mg sensitivity	5
6	Magnetic Stirrers with Thermostat	10
7	Vacuum Pump	1
8	Digital pH meter	1
9	Wall Mounted Water Distillation Unit	2
10	Nessler's Cylinders	40
11	Digital Melting Point Apparatus	2
12	Thieles Tube	20
13	Digital Colorimeter	2
14	Thermostatic Water Bath	1

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

3. Pharmaceutics

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

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

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

Machine Room

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

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

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

4. Hospital and Clinical Pharmacy Lab

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

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

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5. Model Pharmacy

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

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APPENDIX 4

Subject wise list of Recommended Books (Latest Edition)

Pharmaceutics

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

Pharmaceutical Chemistry

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

Pharmacognosy

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

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Human Anatomy and Physiology

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

Social Pharmacy

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

Pharmacology

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

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Community Pharmacy and Management

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

Biochemistry and Clinical Pathology

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

Pharmacotherapeutics

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

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Hospital and Clinical Pharmacy

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

Pharmacy Law and Ethics

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

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