SCHEME OF INSTRUCTION AND SYLLABUS

Diploma in Pharmacy

As per Education Regulation - 2020

w.e.f.2024-25

विद्या कल्पलतेव

Faculty of Pharmacy

United University

Rawatpur-Jhalwa (Prayagraj)

Uttar Pradesh

University Vision

"To establish a Value based Global University having dynamic learning environment encouraging creativity and innovation, research inspired experimental learning and focusing on topics that are pertinent to the development of the region, the Country and the World."

University Mission

- To provide a dynamic, inspiring, and varied learning environment with global exposure.
- To position the institution as a premier hub for research and experiential learning.
- To develop into an adaptable university meeting the demands of society and business.
- To incorporate Value thinking, integrity, wisdom and passion in professional for their career and life.

Department Vision

"To be an organization known for its values, excellence in academics, research and nurturing professionals for pharmacy careers."

Department Mission

M1: To develop competent professionals with ethical & social responsibility.
M2: To prepare students for emerging trends & concepts in pharmaceutical sciences.
M3: To provide state-of-the-art infrastructure and conducive learning environment for academics & research.
M4: To establish & strengthen collaboration between academia & pharmaceutical industries.

Program Educational Objectives

(Diploma)

1. PEO-1:
   To make available a thorough pharmaceutical education leading to D. Pharmacy Degree.

2. PEO-2:
   To impart students with adequate knowledge and skills to perform as health care provider in hospital and community pharmacy.

3. PEO-3:
   To develop trained pharmacists having technical expertise along with strong communication skills and multidisciplinary approach.

4. PEO-4:
   To inculcate systematic approaches about the management of resources and functioning of hospital and community pharmacy.

5. PEO-5:
   To nurture pharmacists to tackle obstacles of pharmacy practice.

Program Outcomes

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

- **PO1-** Demonstrate the knowledge of pharmaceutical and basic sciences in Manufacturing, marketing and healthcare services
- **PO2-** Plan, design, conduct experiments, analyze and interpret data.
- **PO3-** To develop trained pharmacists having technical expertise along with strong communication skills and multidisciplinary approach.
- **PO4-** To inculcate systematic approaches about the management of resources and functioning of hospital and community pharmacy.
- **PO5-** To nurture pharmacists to tackle obstacles of pharmacy practice.
- **PO6-** To ensure persistent development and to participate in life-long learning process for a highly fruitful career.

Program Specific Outcomes

PSO1:

To create pharmacy professional with respect to society & environment with excellence in acquiring knowledge in various field of pharmaceutical sciences.

PSO2:

To create professionals with skills of analyzing and applying the technical knowledge in pharmaceutical industry for research & development of quality medicines.

FACULTY OF PHARMACY

SCHEME OF INSTRUCTION FOR TWO YEAR DIPLOMA PROGRAMME

SCHEME OF INSTRUCTION

COURSE CATEGORY ABBREVIATIONS

1. Program Core-PC
2. Soft Skills-SS
3. Skill Enhancement Course-SEC
4. Compulsory Course-MC
5. Program Elective-PE
6. Open Elective-OE
7. Internship/Project

FACULTY OF PHARMACY

SCHEME OF INSTRUCTION FOR TWO YEAR DIPLOMA PROGRAMME

Table-I: Course of study for Part I

S. No.	Course Code	Course Category	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week	Total Tutorial and Theory/ Practical Hours	Total Tutorial and Theory/ Practical Hours per Week
1.	FPD1DP001T	PC	Pharmaceutics – Theory	75	25	3	1	100	4
2.	FPD1DP001P	PC	Pharmaceutics – Practical	75	-	3	-	75	3
3.	FPD1DP002T	PC	Pharmaceutical Chemistry – Theory	75	25	3	1	100	4
4.	FPD1DP002P	PC	Pharmaceutical Chemistry — Practical	75	-	3	-	75	3
5.	FPD1DP003T	PC	Pharmacognosy – Theory	75	25	3	1	100	4
6.	FPD1DP003P	PC	Pharmacognosy – Practical	75	-	3	-	75	3
7.	FPD1DP004T	MC	Human Anatomy & Physiology — Theory	75	25	3	1	100	4
8.	FPD1DP004P	MC	Human Anatomy & Physiology – Practical	75	-	3	-	75	3
9.	FPD1DP005T	PC	Social Pharmacy – Theory	75	25	3	1	100	4

10.	FPD1DP005P	PC	Social Pharmacy – Practical	75	-	3	-	75	3
11.	PTS1DP001T	SEC	Professional Proficiency	50		1		50	1
			Total	**800**	**125**	**31**	**5**	**925**	**36**

SUBJECT CODE & NAME: FPD1DP001T/ PHARMACEUTICS – THEORY

COURSE OUTCOMES

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

UNIT I:

History of Pharmacy: 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

UNIT II:

Packaging materials: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials

UNIT III:

Pharmaceutical aids: Organoleptic (Colouring, flavouring, and sweetening) agents Preservatives: Definition, types with examples and uses

UNIT IV:

Unit operations: Definition, objectives/applications, principles, construction, and workings of:

Size reduction: hammer mill and ball mill

Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves

Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer

Filtration: Theory of filtration, membrane filter and sintered glass filter

Drying: working of fluidized bed dryer and process of freeze drying

Extraction: Definition, Classification, method, and applications

UNIT V:

Tablets- coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi- layered, etc.)

Capsules - hard and soft gelatine capsules

Liquid oral preparations - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution

Topical preparations - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries, Nasal preparations, Ear preparations

Powders and granules - Insufflations, dusting powders, effervescent powders, and effervescent granules

Sterile formulations – Injectables, eye drops and eye ointments

Immunological products: Sera, vaccines, toxoids, Their manufacturing methods.

Unit VI:

Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants

Quality control and quality assurance: Definition andconcepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation

UNIT VII:

Novel drug delivery systems: Introduction, Classification with examples, advantages, and challenges

SUBJECT CODE & NAME: FPD1DP001P/ PHARMACEUTICS – PRACTICAL

Course Outcomes: Upon successful completion of this course, the students will beable 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 anddispensing 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 specialdosage such as different types of inhalers, spacers, insulin pens
6. Demonstration of quality control tests and evaluation of common dosage formsviz. tablets, capsules, emulsion, sterile injections as per the monographs

Assignments

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

1. Various systems of measures commonly used in prescribing, compounding and dispensing practices
2. Market preparations (including Fixed Dose Combinations) of each type ofdosage 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 theformulation 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.

TEXTBOOKS:

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

SUBJECT CODE & NAME: FPD1DP002T/ PHARMACEUTICAL CHEMISTRY – THEORY

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

1. Describe the chemical class, structure and chemical name of the commonlyused 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 thechemical substances given in the official monographs
4. Identify the dosage form & the brand names of the drugs and pharmaceuticalspopular

in the marketplace

UNIT I:

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.

UNIT II:

Volumetric analysis: Fundamentals of volumetric analysis, Acid-base titration, non-aqueous titration,precipitation titration, complexometric titration, redox titration

Gravimetric analysis: Principle and method.

UNIT III:

Inorganic Pharmaceuticals: Pharmaceuticalformulations, 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

UNIT IV:

Introduction to nomenclature of organic chemical systems with particular reference to heterocyclic compounds containing up to three rings.

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

UNIT V:

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

UNIT VI:

Drugs Acting on Autonomic Nervous System

Sympathomimetic Agents: ***Direct Acting:*** Nor Epinephrine*, Epinephrine, Phenylephrine, Dopamine*, Terbutaline, Salbutamol (Albuterol), Naphazoline*, Tetrahydrozoline. ***Indirect Acting Agents:*** Hydroxy Amphetamine, Pseudoephedrine.Agents With Mixed Mechanism**:** Ephedrine, Metaraminol

Adrenergic Antagonists: Alpha Adrenergic Blockers: Tolazoline, Phentolamine Phenoxybenzamine, Prazosin. Beta AdrenergicBlockers: Propranolol*, Atenolol*, Carvedilol

Cholinergic Drugs and Related Agents: DirectActing Agents: Acetylcholine*, Carbachol, And Pilocarpine. Cholinesterase Inhibitors: Neostigmine*, Edrophonium Chloride, Tacrine Hydrochloride, Pralidoxime Chloride, Echothiopate Iodide

Cholinergic Blocking Agents: Atropine Sulphate*, Ipratropium Bromide

Synthetic Cholinergic Blocking Agents: Tropicamide, Cyclopentolate Hydrochloride, Clidinium Bromide, Dicyclomine Hydrochloride*

UNIT VII:

Drugs Acting on Cardiovascular System

Anti-Arrhythmic Drugs: Quinidine Sulphate,Procainamide Hydrochloride, Verapamil, Phenytoin Sodium*, Lidocaine Hydrochloride, LorcainideHydrochloride, Amiodarone and Sotalol

Anti-Hypertensive Agents: Propranolol*, Captopril*, Ramipril, Methyldopate Hydrochloride, Clonidine Hydrochloride, Hydralazine Hydrochloride, Nifedipine,

Antianginal Agents: Isosorbide Dinitrate

UNIT VIII:

Diuretics: Acetazolamide, Frusemide*, Bumetanide, Chlorthalidone, Benzthiazide,

Metolazone, Xipamide, Spironolactone

UNIT IX:

Hypoglycemic Agents: Insulin and Its Preparations, Metformin*,Glibenclamide*,Glimepiride,Pioglitazone, Repaglinide, Gliflozins, Gliptins

UNIT X:

Analgesic And Anti-Inflammatory Agents: Morphine Analogues, Narcotic Antagonists; ***Nonsteroidal Anti- Inflammatory Agents (NSAIDs)*** - Aspirin*, Diclofenac, Ibuprofen*, Piroxicam, Celecoxib, Mefenamic Acid, Paracetamol*, Aceclofenac

UNIT XI:

Anti-Infective Agents-

Antifungal Agents: Amphotericin-B,Griseofulvin,Miconazole,Ketoconazole*,Itraconazole, Fluconazole*, Naftifine Hydrochloride

Urinary Tract Anti-Infective Agents: Norfloxacin, Ciprofloxacin, Ofloxacin*, Moxifloxacin

Anti-Tubercular Agents: INH*, Ethambutol, ParaAmino 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, Sulfamethoxazole, Sulfacetamide*, Mafenide Acetate, Cotrimoxazole, Dapsone*

UNIT XII:

Antibiotics: Penicillin G, Amoxicillin*, Cloxacillin,Streptomycin, ***Tetracyclines:*** Doxycycline, Minocycline, ***Macrolides:*** Erythromycin, Azithromycin, ***Miscellaneous:*** Chloramphenicol* Clindamycin

UNIT XIII:

Anti-Neoplastic Agents: Cyclophosphamide*, Busulfan, Mercaptopurine, Fluorouracil*, Methotrexate, Dactinomycin, Doxorubicin Hydrochloride, Vinblastine Sulphate, Cisplatin*, Dromostanolone Propionate

SUBJECT CODE & NAME: FPD1DP002P/ PHARMACEUTICAL CHEMISTRY – PRACTICAL

Course Outcomes: Upon successful completion of this course, the students will beable 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 syntheticscheme
5. Perform qualitative tests to systematically identify the unknown chemicalsubstances

Practicals

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 standardizatio 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 iodometryIbuprofen by alkalimetry

5. **Fundamentals of preparative organic chemistry**

   Determination of Melting point and boiling point of organic compounds

6. **Preparation of organic compounds**
   - Benzoic acid from Benzamide
   - Picric acid from Phenol
7. **Identification and test for purity of pharmaceuticals**

   Aspirin, Caffeine, Paracetamol, Sulfanilamide

8. Systematic Qualitative analysis experiments (4 substances)

Assignments

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

1. Differentmonographsandformulariesavailableandtheirmajorcontents
2. Significance of quality control and quality assurance in pharmaceutical industries
3. OverviewonGreenChemistry
4. Varioussoftwareprogramsavailableforcomputeraideddrugdiscovery
5. Variousinstrumentationsusedforcharacterizationandquantificationofdrug

TEXTBOOKS

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

SUBJECT CODE & NAME: FPD1DP003T/ PHARMACOGNOSY – THEORY

Course Outcomes: Upon successful completion of this course, the students will beable 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

UNIT I:

Definition, history, present status and scope of Pharmacognosy

UNIT II:

Classification of drugs:

- Alphabetical
- Taxonomical
- Morphological
- Pharmacological
- Chemical
- Chemo-taxonomical

UNIT III:

Quality control of crude drugs:

- Different methods of adulteration of crude drugs
- Evaluation of crude drugs

UNIT IV:

Brief outline of occurrence, distribution, isolation,identification tests, therapeutic activity and pharmaceutical applications of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.

UNIT V:

Biological source, chemical constituents and therapeutic efficacy of the following categories of crude drugs.

(a) Laxatives- Aloes, Castor oil, Ispaghula, Senna.

(b) Cardiotonics- Digitalis, Arjuna.

(c) Carminatives & G.I. regulators- Coriander, Fennel, Cardamom, Ginger, Clove, Black pepper , Asafoetida, Nutmeg, Cinnamon.

(d) Astringents-Myrobalan, Black Catecheu, Pale Catechu

(e) Drugs acting on nervous system- Hyoscyamus, Belladonna, Ephedra, Opium, Tea Leaves, Coffee seeds, Coca

(f) Antihypertensive- Rauwolfia.

(g) Antitussives- Vasaka, Tolu balsam.

(h) Antirheumatics- Colchicum seed .

(i) Antitumour- Vinca, Podophyllum.

(k) Antidiabetics-Pterocarpus, Gymnema

(l) Diuretics- Gokhru, Punarnava.

(m) Antidysenterics- Ipecacuanha.

(n) Antiseptics and disinfectants- Benzoin, Myrrh, Neem, Curcuma.

(o) Antimalarials- Cinchona, Artemisia

(p) Oxytocics- Ergot.

(q) Vitamins- Cod liver oil, Shark liver oil.

(r) Enzymes- Papaya, Diastase, Pancreatin, Yeast.

(s) Pharmaceutical aids- kaolin, Lanolin, Beeswax, Acacia, Tragacanth, Sodium Alginate, Agar, Guargum, Gelatin.

Miscellaneous- Squill, Galls, Ashwagandha, Tulsi, Guggul

UNIT VI:

Plant fibres used as surgical dressings: Cotton, silk, wool and regenerated fibres Sutures – Surgical Catgut and Ligatures

UNIT VII:

● 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

UNIT-VIII:

Role of medicinal and aromatic plants in national economy and their export potential

UNIT-IX:

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

UNIT-X:

Introduction to herbal formulations

UNIT-XI:

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

UNIT-XII:

Phytochemical investigation of drugs

SUBJECT CODE & NAME: FPD1DP003T/ PHARMACOGNOSY - PRACTICAL

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

1. Identifythegivencrudedrugsbasedonthemorphologicalcharacteristics
2. Takeatransversesectionofthegivencrudedrugs
3. Describe the anatomical characteristics of the given crude drug under microscopical conditions
4. Carryoutthephysicalandchemicalteststoevaluatethegivencrudedrugs

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.

TEXTBOOKS

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

SUBJECT CODE & NAME: FPD1DP004T/ HUMAN ANATOMY AND PHYSIOLOGY – THEORY

Course Outcomes: Upon successful completion of this course, the students will beable 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 thehuman system
4. Discuss the significance of various vital physiological parameters of thehuman body

UNIT I:

Scope of Anatomy and Physiology, Definition of various terminologies

UNIT II:

Structure of Cell: Components and its functions

UNIT III:

Tissues of the human body: Epithelial, Connective Muscular and Nervous tissues their sub-types and characteristics

UNIT IV:

Osseous system: structure and functions of bones of axial and appendicular skeleton Classification, types and movements of joints, disorders of joints

UNIT V:

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

UNIT VI:

Lymphatic system Lymph and lymphatic system, composition, function and its formation.

Structure and functions of spleen and lymph node.

UNIT VII:

Cardiovascular system

- Anatomy and Physiology of heart
- Blood vessels and circulation (Pulmonary, coronary andsystemic circulation)

- Cardiac cycle and Heart sounds, Basics of ECG

Blood pressure and its regulation

UNIT VIII:

Respiratory system

- Anatomy of respiratory organs and their functions.
- Regulation, and Mechanism of respiration.

Respiratory volumes and capacities – definitions

UNIT IX:

Digestive system

- Anatomy and Physiology of the GIT
- Anatomy and functions of accessory glands

Physiology of digestion and absorption

UNIT X:

Skeletal muscles

- Histology
- Physiology of muscle contraction
- Disorder of skeletal muscles

UNIT XI:

Nervous system

- Classification of nervous system
- Anatomy and physiology of cerebrum, cerebellum, midbrain
- Function of hypothalamus, medulla oblongata and basalganglia
- Spinal cord-structure and reflexes
- Names and functions of cranial nerves.
- Anatomy and physiology of sympathetic and parasympathetic nervous system (ANS)

UNIT XII:

Sense organs - Anatomy and physiology of

- Eye
- Ear
- Skin

- Tongue Nose

UNIT XIII:

Urinary system

- Anatomy and physiology of urinary system
- Physiology of urine formation
- Renin - angiotensin system

Clearance tests and micturition

UNIT XIV:

Endocrine system (Hormones and their functions)

- Pituitary gland
- Adrenal gland
- Thyroid and parathyroid gland
- Pancreas and gonads

UNIT XV:

- Anatomy of male and female reproductive system
- Physiology of menstruation
- Spermatogenesis and Oogenesis
- Pregnancy and parturition

SUBJECT CODE & NAME: FPD1DP004T/ HUMAN ANATOMY AND PHYSIOLOGY – PRACTICAL

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

1. Perform the haematological tests in human subjects and interpret the results
2. Record, monitor and document the vital physiological parameters of humansubjects 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

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

TEXTBOOKS

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

SUBJECT CODE & NAME: FPD1DP004T/ SOCIAL PHARMACY – THEORY

Course Outcomes: Upon successful completion of this course, the students will beable 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

UNIT I:

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.
- Concept of Health -WHO Definition, various dimensions, determinants, and health Indicators.
- National Health Policy – Indian perspective
- Public and Private Health System in India,National Health Mission
- Introduction to Millennium Development Goals, Sustainable Development Goals, FIP Development goals

UNIT II:

Preventive healthcare – Role of Pharmacists in the following:

- Demography and Family Planning
- Mother and child health, importance of breastfeeding, illeffects of infant milk substitutes and bottle feeding.
- Overview of Vaccines, types of immunity andimmunization
- 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 pollutiondue to pharmaceuticals
- Psychosocial Pharmacy: Drugs of misuse and abuse —psychotropics, narcotics, alcohol, tobacco products.Social Impact of these habits on social health and productivity and suicidal behaviors

UNIT-III:

Nutrition and Health

- Basics of nutrition – Macronutrients and Micronutrients
- Importance of water and fibres in diet
- Balanced diet, Malnutrition, nutrition deficiency diseases, ill effects of junk foods, calorific and nutritive values of various foods, fortification of food
- Introduction to food safety, adulteration of foods, effects of artificial ripening, use of pesticides,

geneticallymodified foods

- Dietary supplements, nutraceuticals, food supplements– indications, benefits, Drug-Food Interactions

UNIT IV:

Introduction to Microbiology and common micro-organisms:

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,
- 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
  Intestinal infections — poliomyelitis, viral hepatitis, cholera, acute diarrheal diseases, typhoid, amebiasis, worm infestations, food poisoning
- Arthropod-borne infections - dengue, malaria, filariasisand, chikungunya
- Surface infections – trachoma, tetanus, leprosy STDs, HIV/AIDS

UNIT V:

Introduction to health systems and **all ongoing NationalHealth programs** in India, their objectives, functioning, outcome, and the role of pharmacists.

UNIT VI:

Pharmacoeconomics – Introduction, basic terminologies, importance of pharmacoeconomics

:

SUBJECT CODE & NAME: FPD1DP004T/ SOCIAL PHARMACY – PRACTICAL

Course Outcomes: Upon successful completion of this course, the students will beable 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):

Practical

1. National immunization schedule for children, adult vaccine schedule, Vaccineswhich are not included in the National Immunization Program.
2. RCH – reproductive and child health – nutritional aspects, relevant nationalhealth 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 andsneeze 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 CardiacArrest, FBAO - Foreign Body Airway Obstruction, CPR, Defibrillation (using AED) (Includes CPR techniques, First Responder).
10. Emergency treatment for all medical emergency cases viz. snake bite, dog bite, insecticide poisoning, fractures, burns, epilepsy etc.
11. Role of Pharmacist in Disaster Management.
12. Marketed preparations of disinfectants, antiseptics, fumigating agents, antilarval agents, mosquito repellents, etc.
13. Health Communication: Audio / Video podcasts, Images, Power Point Slides, Short

Films, etc. in regional language(s) for mass communication / education / Awareness on 5 different communicable diseases, their signs and symptoms, and prevention.

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

Assignment

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

1. An overview of Women's Health Issues
2. Study the labels of various packed foods to understand their nutritionalcontents
3. Breastfeeding counselling, guidance – using Information, Education and Communication (IEC)
4. Information about the organizations working on de-addiction services in theregion (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 withdisabilities
7. Primary health care centre

TEXTBOOKS

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

SUBJECT CODE & NAME: PTS1DP001T/ PROFESSIONAL PROFICIENCY-THEORY

Course Outcomes

1. Better representation of himself/ herself regarding communication skills, overall personality development, and aptitude building required for jobs.
2. This program will help students become employable and ready for Industries/ corporate and other Public and Private Sector jobs.

UNIT I:

HARD skill:

Revision of Parsing, Preposition (difficult level), Idioms and Phrasal Verbs, Reported Speech, Interchange of Affirmative and Negative Sentences, interchange of Interrogative and Assertive Sentences

UNIT II:

SOFT SKILL:

Powerpoint Presentations, Group Discussions, and debate

Conversation exercises including Each student should speak for 5 minutes, 3-4 times in 1st semester on topics of his choice selected from Social, Environmental, Sports, Business and Economics, Medicines and Health Care, Science and Technology, Politics, World Affairs, and Religion, etc.

UNIT III:

Practice Sheet

Questions (Subjective and Objective) based on the instruction given for hard skills to be distributed every week.

The aim should be to bring the instruction given in practice by making them write, speak and think along the lines of the instruction given. The practice sheet should be evaluated and necessary feedback must be given. Some exercise on compositional skills must be given so that they develop a sense of writing and expressing themselves through the written word.

UNIT IV:

LOGICAL REASONING

1. Simplification & Approximation. 2. Number Series. 3. Alphabetical Series.4.Coding-Decoding

TEXTBOOKS:

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010

7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011

8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011

9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011

10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011.

FACULTY OF PHARMACY

SCHEME OF INSTRUCTION FOR TWO YEAR DIPLOMA PROGRAMME

Table-I: Course of study for Part II

S. No.	Course Code	Course Category	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week	Total Tutorial and Theory/ Practical Hours	Total Tutorial and Theory/ Practical Hours per Week
1.	FPD2DP001T	PC	Pharmacology – Theory	75	25	3	1	100	4
2.	FPD2DP001P	PC	Pharmacology – Practical	50	-	2	-	50	2
3.	FPD2DP002T	PC	Community Pharmacy& Management — Theory	75	25	3	1	100	4
4.	FPD2DP002P	PC	Community Pharmacy& Management — Practical	75	-	3	-	75	3
5.	FPD2DP003T	MC	Biochemistry & Clinical Pathology – Theory	75	25	3	1	100	4
6.	FPD2DP003P	MC	Biochemistry & Clinical Pathology – Practical	50	-	2	-	50	2
7.	FPD2DP004T	PC	Pharmacotherapeutics – Theory	75	25	3	1	100	4

8.	FPD2DP004P	PC	Pharmacotherapeutics – Practical	25	-	1	-	25	1
9.	FPD2DP005T	PC	Hospital & Clinical Pharmacy – Theory	75	25	3	1	100	4
10.	FPD2DP005P	PC	Hospital & Clinical Pharmacy – Practical	25	-	1	-	25	1
11.	FPD2DP006T	PC	Pharmacy Law & Ethics	75	25	3	1	100	4
Total				**675**	**150**	**27**	**6**	**825**	**33**

FPD2DP001T/ Pharmacology – THEORY

Course Outcomes:

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

UNIT I:

General Pharmacology :-Introduction and scope of Pharmacology Various routes of drug administration - advantages anddisadvantages**.** 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.

UNIT II:

Drugs Acting on the Peripheral Nervous System: -Steps involved in neurohumoral transmission Definition, classification, pharmacological actions, dose,indications, and contraindications of Cholinergic drugs, Anti-Cholinergic drugs, Adrenergic drugs, Anti-adrenergic drugs, Neuromuscular blocking agents, Drugs used in Myasthenia gravis, Local anesthetic agents, Non-SteroidalAnti-Inflammatory drugs(NSAIDs)

UNIT III

Drugs Acting on the Eye: - Definition, classification, pharmacological actions, dose,indications and contraindications of Miotics**,** Mydriatics, Drugs used in Glaucoma

UNIT IV:

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

UNIT V

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.

UNIT VI

Drugs Acting on Blood and Blood Forming Organs Definition, classification, pharmacological actions dose, indications, and contraindications of Hematinic Agents Anti-sCoagulants Anti-platelet agents Thrombolytic drug

UNIT VII

Definition, classification, pharmacological actions, dose,indications, and contraindications of Bronchodilators Expectorants Anti-tussive agents Mucolytic agents

UNIT VIII

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

UNIT IX

Drugs Acting on the Kidney:-Definition, classification, pharmacological actions, dose,indications, and contraindications of Diuretics, Anti-Diuretics

UNIT X

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

UNIT XI

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

UNIT XII

Chemotherapeutic Agents: - Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication andcontraindications 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

UNIT XII

Biologicals

Definition, types, and indications of biological agents withexamples.

TEXTBOOKS

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

FPD2DP001P PHARMACOLOGY – PRACTICAL

Course Outcomes:

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

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

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

FPD2DP002T COMMUNITY PHARMACY AND MANAGEMENT – THEORY

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

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

UNIT I:

Community Pharmacy Practice — Definition, history anddevelopment of community pharmacy - International and Indian

Scenarios

UNIT II:

Professional responsibilities of community pharmacists. Introduction to the concept of Good Pharmacy Practice andSOPs

UNIT III:

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,

UNIT IV:

Communication skills: Definition, types of communication skills, Interactions with professionals and patients, Verbal communication skills (one-to-one, over thetelephone)Written communication skills, Body language, Patient interview techniques.

UNIT V:

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 chronicdiseases/disorders** - Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, andAIDS**, Patient Package Inserts** - Definition, importance and benefits, Scenarios of PPI use in India and other countries, **Patient Information leaflets** -

Definition and uses

UNIT VI:

Medication Adherence: Definition, factors influencing non- adherence, strategies toovercome non-adherence

UNIT VII:

Health Screening Services in Community Pharmacy Introduction, scope, and importance of various health screeningservices - for routine monitoring of patients, early detection, and referral of undiagnosed cases

UNIT VIII:

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.

UNIT IX:

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 inventorymanagement, Financial planning and management, Accountancy in community pharmacy – Day book, Cashbook, Introduction to pharmacy operation soft wares – usefulnessand availability, Customer Relation Management (CRM), Audits in Pharmacies, SOP of Pharmacy Management, Introduction to Digital Health, Healthand Onlinepharmacies

FPD2DP002P COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

Course Outcomes: Upon successful completion of this course, the students will beable 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

Note: The following practicals shall be carried out in the model community pharmacywith 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 prescribedmedications (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 eachdisease)

   Type 2 Diabetes Mellitus, Primary Hypertension, Asthma,Hyperlipidaemia, Rheumatoid Arthritis

6. Providing counselling to simulated patients for the following minor ailments (any three)

Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.

7 Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers,Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
8 Use of Community Pharmacy Software and digital health tools

Assignments

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

1. SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)
2. List out the various abbreviations, short forms used in prescriptions and their interpretation
3. Patient Information Leaflet for a given chronic disease / disorder
4. Patient Information Leaflet for prescription / non-prescription medicines
5. Preparation of window / shelf display materials for the model communitypharmacy
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 onlinepharmacies
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.

TEXT BOOK

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 /publication

FPD2DP003T/ Biochemistry & Clinical Pathology – THEORY

Course Outcomes:

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

UNIT I:

Introduction to biochemistry: Scope of biochemistry in

pharmacy; Cell and its biochemical organization.

UNIT II:

Carbohydrates:-Definition, classification with examples, chemicalproperties, Monosaccharides - Structure of glucose, fructose, andgalactose, Disaccharides - structure of maltose, lactose, andsucrose, Polysaccharides - chemical nature of starch andglycogen, Qualitative tests and biological role of carbohydrates

UNIT III:

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.

UNIT IV:

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 thebody, Qualitative tests and functions of lipids

UNIT V:

Nucleic acids Definition, purine and pyrimidine bases, Components of nucleosides and nucleotides withexample Structure of DNA (Watson and Crick model), RNA and their functions

UNIT VI:

Enzymes

Definition, properties and IUB and MB classification, Factors affecting enzyme activity, Mechanism of action of enzymes Enzyme inhibitors, Therapeutic and pharmaceutical importance ofenzymes.

UNIT VII:

Vitamins Definition and classification with examples, Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins

UNIT VIII:

Metabolism (Study of cycle/pathways without chemical structures), Metabolism of Carbohydrates: Glycolysis, TCA cycle and glycogen metabolism, regulation of blood glucose level. Diseases related to abnormal metabolism of Carbohydrates,

Metabolism of lipids: Lipolysis, β-oxidation of Fatty acid(Palmitic acid) ketogenesis and ketolysis. Diseases related to abnormal metabolism of lipids such as Ketoacidosis, Fatty liver, Hypercholesterolemia, Metabolism of Amino acids (Proteins): General reactions of amino acids and its significance–Transamination, deamination, Urea cycle anddecarboxylation. Diseases related to abnormal metabolism of amino acids, Disorders of ammonia metabolism, phenylketonuria, alkaptonuria and Jaundice. Biological oxidation: Electron transport chain and Oxidative phosphorylation.

UNIT IX:

Minerals: Types, Functions, Deficiency diseases, recommended dietary

requirements

UNIT X:

Water and Electrolytes Distribution, functions of water in the body, Water turnover and balance, Electrolyte composition of the body fluids, Dietaryintake of electrolyte and Electrolyte balance, Dehydration, causes of dehydration and oral rehydration therapy

UNIT XI:

Introduction to Biotechnology

UNIT XII:

Organ function tests: - **Functions of kidney and routinel 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.**

UNIT XIII:

Introduction to Pathology of Blood and Urine: - Lymphocytes and Platelets, their role in health anddisease, Erythrocytes Abnormal cells and their significance, Normal and Abnormal constituents of Urine and theirsignificance.

FPD2DP003P/ Biochemistry & Clinical Pathology – PRACTICAL

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

1. Qualitatively determine the biomolecules / metabolites in the given biological samples
2. Determine the normal and abnormal constituents in blood and urine samplesand 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 PathologyLab Reports (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student).

TEXTBOOKS

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

FPD2DP004T /Pharmacotherapeutics - THEORY

Course Outcomes:

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

UNIT I:

Pharmacotherapeutics – Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs

UNIT II:

Definition, etiopathogenesis, clinical manifestations, non-pharmacological and pharmacological management of thediseases associated with: -

Cardiovascular System Hypertension, Angina and Myocardial infarction, Hyperlipidemia, Congestive Heart Failure.
Respiratory System Asthma, COPD
Endocrine System Diabetes, Thyroid disorders - Hypo and Hyperthyroidism
Central Nervous System Epilepsy, Parkinson's disease**,** Alzheimer's disease**,** Stroke, Migraine
Gastro Intestinal Disorders Gastro oesophageal reflux disease, Peptic Ulcer Disease, Alcoholic liver disease,

Inflammatory Bowel Diseases (Crohn's Disease andUlcerative Colitis).

Hematological disorders Iron deficiency anemia, Megaloblastic anemia

Infectious diseases Tuberculosis, Pneumonia, Urinary tract infections, Hepatitis, Gonorrhea and Syphilis, Malaria, HIV and Opportunistic infections, Viral Infections (SARS, CoV2).

Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis

Dermatology Psoriasis, Scabies, Eczema.
Psychiatric Disorders Depression, Anxiety, Psychosis
Ophthalmology Conjunctivitis (bacterial and viral,) Glaucoma,
Anti-microbial Resistance

Women's Health Polycystic Ovary Syndrome, Dysmenorrhea, Premenstrual Syndrome

FPD2DP004P/ Pharmacotherapeutics – Practical

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 ofhandling 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)

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)

TEXTBOOKS

1. 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. 5. National Formulary of India, Indian Pharmacopoeia Commission, Ghaziabad.

FPD2DP005T/ Hospital And Clinical Pharmacy – Theory

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

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

UNIT I:

Hospital Pharmacy

Definition, scope, national and international scenario, Organisational structure, Professional responsibilities, Qualification and experiencerequirements, 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

UNIT II:

Different Committees in the Hospital Pharmacy and Therapeutics Committee - Objectives, Composition, and functions, HospitalFormulary - — Definition, procedure for development and use of hospital formulary,

UNIT III:

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. Disposalof Narcotics, cytotoxic drugs

Documentation - purchase and inventory

UNIT IV:

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

UNIT V:

Compounding in Hospitals. Bulk compounding, IV admixture Services and incompatibilities, Total parenteral nutrition

UNIT VI:

Radio Pharmaceuticals - Storage, dispensing and disposal of radiopharmaceuticals

UNIT VII:

Application of computers in Hospital Pharmacy Practice, Electronic health records, Software used in hospital pharmacy

UNIT VIII:

Clinical Pharmacy: Definition, scope, and development - in India and other countries. Technical definitions, common terminologies used in clinical settings and their significance such as Pediatrics, Geriatric, Anti-natal Care, Post-natal Care

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**

UNIT X:

Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results Hematological, Liver function, Renal function, thyroidfunction tests, Tests associated with cardiac disorders, Fluid and electrolyte balance, Pulmonary Function Tests

UNIT XI:

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

UNIT XII:

Pharmacovigilance Definition, aim and scope, Overview of Pharmacovigilance

UNIT XIII:

Medication errors: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs andTallman lettering as per ISMP **Drug Interactions:** Definition, types, clinical significance of druginteractions

FPD2DP005P/ Hospital And Clinical Pharmacy – Practical

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 aidsand devices
5. Interpret and report the drug-drug interactions in common diseases foroptimizing the drug therapy

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

Practical

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

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

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

Assignments

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

1. Typical profile of a drug to be included in the hospital formulary
2. Brief layout and various services of the Central Sterile Supplies Department(CSSD)
3. Various types of sterilizers and sterilization techniques used in hospitals
4. Fumigation and pesticide control in hospitals
5. Role of Pharmacists in Transition of Care: Discharge cards, post hospitalizationcare, 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, 2DECHO, 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 servicesprovided. Individual reports from each student on their learning experience from the field visit shall be submitted.

TEXTBOOKS

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.

FPD2DP006T /Pharmacy Law And Ethics – Theory

Course Outcomes: Upon successful completion of this course, the students will beable 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 inIndia
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

UNIT I:

General Principles of Law, History and various Acts related to Drugs and Pharmacy profession

UNIT II:

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

UNIT III:

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 andcosmetics prohibited from import, Import under license or permit.

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

UNIT IV:

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

UNIT V:

Drugs and Magic Remedies (ObjectionableAdvertisements) Act 1954
Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements,
Offences and Penalties

UNIT VI:

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.

UNIT VII:

Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison,import of poisons

UNIT VIII:

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

UNIT IX:

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)

UNIT X:

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.

UNIT XI:

Medical Termination of Pregnancy Act and Rules – basicunderstanding, salient features, and Amendments

UNIT XII:

Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC

UNIT XIII:

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

UNIT XIV:

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

UNIT XV:

Blood bank – basic requirements and functions

UNIT XVI:

Clinical Establishment Act and Rules – Aspects related to Pharmacy

UNIT XVII:

Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals

UNIT XVIII:

Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants

UNIT XIX:

Introduction to the Consumer Protection Act

UNIT XX:

Introduction to the Disaster Management Act

UNIT XXI:

Medical Devices – Categorization, basic aspects related to manufacture and sale

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 Generic Medicines

TEXTBOOKS

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 Mohant