Course curriculum

Bachelor of Pharmacy (Practice) [B. Pharm. (Practice)] BRIDGE COURSE

Pathophysiology and Pharmacotherapeutics - I

Scope:
Practicing pharmacists will have opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:
Upon completion of the course, the student will be able to
(a) Understand the anatomy and physiology of the respective system
(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages.

Course duration:

Learning
40 hours of learning by blended mode of teaching. Blended teaching includes didactic and onsite learning.

Case Presentations
During the course each student should present 5 cases covering the diseases prescribed in the syllabus.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Schedules

1. Introduction to pathophysiology and therapeutics – scope and objectives - 1 hr

2. Prescribing guidelines (Drug and dosage selection and dose calculation) for - 4 hrs
   (a) Pediatrics
   (b) Geriatrics
   (c) Pregnant and breast feeding women
   (d) Renally and hepatically challenged patients

3. Elements of anatomy, etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Cardiovascular System -15 hrs
   (a) Hypertension
(b) Ischemic Heart diseases (Angina and Myocardial Infarction)
(c) Hyperlipidemia
(d) Congestive Heart Failure
(e) Arrhythmias

4. Elements of anatomy, Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Respiratory System - 12 hrs
   (a) Asthma
   (b) COPD
   (c) Drug induced pulmonary diseases

5. Elements of anatomy Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Endocrine System - 8 hrs
   (a) Diabetes.
   (b) Thyroid diseases

Books/References:
Suggested Assignments:
Pathophysiology and Pharmacotherapeutics - II

Scope:
Practicing pharmacists will have the opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:

Upon completion of the course, the student will be able to
(a) Understand the anatomy and physiology of respective system
(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages.

Course duration:
Learning
(a) 40 hours of learning by blending method.
(b) Blended mode of education and includes didactic and onsite learning.

Case Presentations
During the course each student should present 5 cases covering the diseases prescribed in the syllabus.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Schedules

1. Elements of anatomy, Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with CNS - 18 hr
   (a) Anxiety
   (b) Depression
   (c) Schizophrenia,
   (d) Manic depressive disorders
   (e) Epilepsy,
   (f) Parkinson’s disease,
   (g) Headaches

2. Elements of anatomy, Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with GI Disorders 10 hrs
   (a) Dyspepsia,
   (b) Acid Pepsin Disease,
   (c) Inflammatory Bowel Disease.
   (d) Liver disorders- Hepatitis, Gall stones, Alcoholic Liver Disease.
3. Elements of anatomy, etiopathogenesis, clinical manifestations and pharmacotherapeutics of diseases associated with hematological System - 8 hrs
   Erythropoietic system – Over view, Iron deficiency anemia, Megaloblastic anemia, Sideroblastic anemia, Hemolytic anemia, Venous Thromboembolism, Arterial Thromboembolism, Drug induced blood disorders.

Books and references
Suggested topics for assignment
Pharmacy Practice - I

Scope
Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in community settings through counselling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and provide all hospital pharmacy services including clinical pharmacy services such as drug information and ADR reporting.

Objectives:

Upon completion of the course, the student will be able to
(a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
(b) Understand the professional responsibilities of the pharmacists.
(c) Provide the intended services.

Course duration:

Learning
40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Schedules

1. Introduction to Pharmacy Practice
   Definition, patient focused approach, scope/areas of practice - 1 hour

2. Introduction to Clinical Pharmacy - 3Hrs
   (a) Definition, Scope, Objectives of Clinical Pharmacy Practice
   (b) International v/s National scenario
   (c) Professional responsibilities of Clinical Pharmacists.

3. Clinical Pharmacy daily activities - 6 hrs
   (a) Definition, objectives and procedures of
      (i) Ward round participation
      (ii) Treatment chart review
      (iii) Drug information
      (iv) Patient counseling
      (v) ADR monitoring and reporting
      (vi) Therapeutic drug monitoring.
      (vii) Home Medication Review
   (b) Patient Data analysis - 02 hours
      Patient case history, drug therapy evaluation, identification and resolving of drug related problems.
4. Practice Management : - 08 hrs
   (a) Professional practice standards - Good Pharmacy Practice – in detail including Good storage practice, good dispensing practices, etc. (national and international scenario) (for both community and hospital pharmacy)
   (b) Pharmacy Practice Regulations (PCI), Code of Ethics for Pharmacists
   (c) SOPs, writing SOPs, Documentation, writing various record formats for community and hospital pharmacy, validation of various processes in Hospital & Community Pharmacy.
   (d) Concept of Accreditation of Pharmacies
   (e) Validation concepts & instruments for community pharmacy and hospital pharmacy
   (f) Concept of Audits in community and hospital pharmacy

5. Hospital and Hospital Pharmacy Organisation - 6 Hrs
   (a) Definition of Hospital, Hospital Pharmacy, Organizational Structure of Hospital, Hospital Pharmacy, professional roles and responsibilities of hospital pharmacist.
   (c) International scenario vs Indian Scenario of Hospital Pharmacy Practice.
   (d) Hospital Pharmacy Practice - Requirements for functioning of hospital pharmacy, Qualification and experience requirements for pharmacists, work load statistics.
   (e) Standards of Pharmacies in hospitals

6. Drug Committees - 4 Hrs
   Pharmacy and Therapeutics Committee, Hospital Formulary, Infection Control committee, Institutional Review Board.

7. Community Pharmacy - 8 hrs
   (a) Definition, scope and professional responsibilities of community pharmacist.
   (b) International scenario vs Indian Scenario of Community Pharmacy Practice
   (c) Pharmacy Assistant/Technician/Salesperson – roles and responsibilities,
   (d) Community pharmacist’s services to other health care professionals, and to nursing homes

8. Community Pharmacy Management - 4 hrs
   Selection of site, legal requirements, procurement, storage, and inventory control, product display, finance management.

Books and references
Suggested assignment topics
Pharmacy Practice II

Scope
Practicing pharmacists have opportunity to provide various patient care services to improve the patient’s health in community settings through counseling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and provide all hospital pharmacy services including clinical pharmacy services such as drug information and ADR reporting.

Objectives:
Upon completion of the course, the student will be able to
(a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
(b) Understand the professional responsibilities of the pharmacists.
(c) Provide the intended services.

Course duration:
Learning
40 hours of learning by blending method.
Blended teaching includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time of Final Examination.

Detailed syllabus and lecture wise teaching schedules
1. Hospital Pharmacy Stores Management - 04 hours
Stores Management, Drug Purchase and Procurement, Inventory Control and GPP. Management of Material and Finance.

2. Drug Dispensing and Drug Distribution - 8 hours
Drug distribution – various methods, individual order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug basket method, Distribution to ICCU/ICU/Emergency wards, Automated drug dispensing systems and devices, Distribution of Narcotic and Psychotropic substances, GPP associated with all these.

3. Central Sterile Supply Services - 2 hours

4. Prescription and prescription handling - 5 hours
(a) Definition, Parts of prescriptions, good prescribing practices, legality of prescriptions, identification of drug related problems in prescriptions.
(b) Prescription handling, labeling of dispensed medications (Main label, Ancillary label, pictograms), Medication usage instructions.
(c) Good dispensing practices
(d) Drug Interactions (Drug-Drug, Drug-Food, Drug-Lab investigations) – types, interpretation and detection, prevention, Practice on market prescriptions, Use of drug interaction software’s.
5. **Pharmaceutical Care - 02 hours**
Definition, principles and procedures of pharmaceutical care

6. **Patient Counseling - 04 hours**
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Definition, various stages of patient counseling, barriers in counseling and strategies to overcome barriers in patient counseling. Patient information leaflets- definition, layout and design of PILs.

7. **Health Screening Services - 04 hours**
Definition, scope, and uses of health screening services, procedures involved in screening blood pressure, capillary blood glucose, body mass index

8. **Interpretation of laboratory data - 10 hours**
(a) Haematological, Liver function, Renal function, thyroid function tests
(b) Tests associated with cardiac disorders
(c) Fluid and electrolyte balance
(d) Microbiological culture sensitivity tests
(e) Pulmonary Function Tests

Books and references
suggested topics for assignments
Applied Pharmaceutics

Scope
This course is designed to impart a fundamental knowledge on different dosage forms and pharmacokinetic changes in the body. It helps the student to understand the basic concepts regarding, absorption, distribution, metabolism and excretion.

Objectives
Upon completion of the course, the student shall be able to—
(a) Understand the formulation principles of various dosage forms
(b) Understand the basic principles of stability, storage and administration of various dosage forms
(c) Learn above novel drug delivery systems
(d) Understand various pharmacokinetic pathways and optimize the drug therapy.
(e) Understand Pro Drugs concept.

Course duration:

Learning
40 hours of learning by blended teaching. Blending teaching includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering Pharmaceutical Dosage forms and Pharmacokinetic concepts

Text Books
(a) Cooper and Gunns Dispensing for pharmacy students.
(b) A text book Professional Pharmacy by N. K. Jain and S. N. Sharma.

Reference Books
(a) Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
(b) Remington’s Pharmaceutical Sciences

Lecture wise program and detailed syllabus
1. Introduction to Pharmaceutical Dosage Forms - 1 hr
2. Basics of GMP, GLP, QA, QC - 1 hr
3. Study the following about all dosage forms : - 15 hrs
   (a) Need, advantage, disadvantages
   (b) Brief of various ingredients used and need for these, basic properties of inactives. Basic overview of manufacturing without going into details.
   (c) Storage, packaging requirements
   (d) Possible stability and defects issues
   (e) Proper use, special precautions while using, instructions to patients
   (f) Bioavailability/biopharmaceutics aspects
4. Introduction to Novel drug delivery systems, instructions to be given to patients – Transdermal, infusion pumps, genetically engineered medicines, etc. - **6 hrs**

5. Introduction to Bio-Pharmaceutics - **1 hr**

6. Absorption of drugs - **3 hrs**
   (a) Introduction to absorption, structure and physiology of cell membrane
   (b) Factors affecting drug absorption, Absorption of drugs from extra vascular routes.

7. Distribution of Drugs - **2 hrs**
   (a) Tissue permeability of drugs, Physiological barriers to drug distribution.
   (b) Factors affecting drug distribution.
   (c) Volume of drug distribution, Drug protein, drug tissue binding.

8. Biotransformation of drugs - **3 hrs**
   (a) Drug metabolizing organs and Enzymes
   (b) Phase I reactions, Phase II reactions
   (c) Factors affecting biotransformation of the drugs

9. Excretion of drugs - **1 hour**
   Renal excretion of drugs, Factors affecting the renal filtration, Non renal routes of drug excretion

10. Prodrugs - **1 hour**
    Definition and applications of pro-drugs

11. Bioavailability and Bioequivalence - **4 hours**
    (a) Definition of bioavailability and bioequivalence
    (b) Factors affecting bioavailability.
    (c) Importance of BA, BE, BA Classification system, NTI drugs, care to be taken in prescribing and dispensing of such drugs

**Assignments**
Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination
Social Pharmacy – I

Scope:
Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in the society. By monitoring the health of the individuals, providing them education about health, precautions, and pharmacists can improve their professional image.

Objectives:
Upon completion of the course, the student will be able to
(a) Understand the social responsibility of the pharmacists in the society
(b) Understand the health policies
(c) Provide health care services to patients.

Course duration:

Learning
40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts

Detailed syllabus and topics

1. Introduction to Social Pharmacy –
   (a) Definition and Scope - Introduction to Social Pharmacy as a discipline and its various concepts. Sociological Understanding of Health and Illness, Role of Pharmacist in Public Health - 1hr
   (b) WHO Definition of health – various dimensions of health - 1 hr
   (c) Introduction and broad overview of health systems, infrastructure, and functioning in India and other countries – both in Public and private sector. National health programmes in India – brief study of these and the role of pharmacist in each of these. - 5 hrs

2. Drugs, Industry & Policies - 7 hrs
   (a) Drugs and developed countries, developing countries, GATT, patents, Patents Act.
   (b) Pharmaceutical Industry and its activities, Classification systems of drugs, Social marketing – brief study of organizations and functioning like Medicines Sans Frontiers
   (c) Concept of RUM, WHO Essential Medicines, Irrational medicine use and its associated problems, etc., Evidence based medicine, STGs (Standard Treatment Guidelines)
   (d) National Drug Policy, National Health Policy, Pharmacy & Drug Ethics –

3. Pharmacoeconomics – Definition, types of pharmaco economic models, consumption of drugs, pharmaceutical pricing and reimbursement, Health Insurance - 3 hrs
4. **Pharmacoepidemiology** – Definition, scope, advantages and disadvantages. - 3 hrs

5. **Health Promotion and Health education - 20 hrs**
Epidemiology of Communicable Diseases: Causative agents and Clinical presentations and Role of Pharmacist in prevention of communicable diseases:
(a) Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis
(b) Intestinal infections – poliomyelitis, viral hepatitis, cholera, acute diarrhoeal diseases, typhoid, food poisoning, amebiasis, worm infestations
(c) Arthropod-borne infections - dengue, malaria, filariasis and, chikungunya
(d) Zoonoses – rabies, yellow fever, Japanese encephalitis, plague, human salmonellosis, ricketsial diseases, taeniasis, hydatid disease, leishmaniasis
(e) Surface infections – trachoma, tetanus, leprosy, STDs, HIV/AIDS
(f) Emerging and reemerging infectious diseases.

**Text books (Theory)**
2. *Text Book of Community Pharmacy Practice*. RPSGB Publication
Pathophysiology and Pharmacotherapeutics - III

Scope:
Practicing pharmacists will have opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:
Upon completion of the course, the student will be able to
(a) Understand the anatomy and physiology of the respective system
(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages

Course duration:

Learning
40 hours of learning by blended teaching. Blended teaching includes didactic and onsite learning.

Case Presentations
During the course each student should present 5 cases covering the diseases prescribed in the syllabus.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and Lecture wise schedules

1. Infectious diseases: - 25 Hours
   (a) Guidelines for the rational use of antibiotics and surgical Prophylaxis.
   (b) Pathophysiology and Pharmacotherapeutics of Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis

2. Musculoskeletal disorders - 08 Hrs
   (a) Basics of Anatomy and physiology of musculoskeletal system.
   (b) Pathophysiology and Pharmacotherapeutics of Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic Lupus Erythematosus

3. Renal system - 07 Hrs
   (a) Basics of anatomy and physiology of Renal system
   (b) Pathophysiology and pharmacotherapeutics of Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
Pathophysiology and Pharmacotherapeutics - IV

Scope:
Practicing pharmacists will have opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:

Upon completion of the course, the student will be able to:
(a) Understand the anatomy and physiology of the respective system
(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages

Course duration:

Learning
40 hours of learning by blended teaching. Blended teaching includes didactic and onsite learning.

Case Presentations
During the course each student should present 5 cases covering the diseases prescribed in the syllabus.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Wise Program

1. Oncology: - 15 Hrs
   (a) Basic principles of Cancer therapy,
   (b) General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia.
   (c) Management of chemotherapy induced nausea and emesis

2. Dermatology: - 7 Hrs
   Pathophysiology and Pharmacotherapeutics of Psoriasis, Scabies, Eczema, Impetigo

3. Women’s Health - 10 Hrs
   (a) Physiology of Menstrual Cycle
   (b) Contraception – Physical Methods, Chemical Methods, IUDs, and Permanent methods.
   (c) Disorders related to Menstrual Cycle – Polycystic ovary Syndrome, Dysmenorrhea, Premenstrual Syndrome.
   (d) Obstetric Drug Therapy – Trimesters of Pregnancy, Common complaints of Pregnancy and their management – nausea, vomiting, reflex esophagitis,
Diabetes mellitus, Hypertension and Preeclampsia, FDA Categorisation of drugs in Pregnancy
(e) Menopause – signs and symptoms and Management

4. **Elements of anatomy and Physiology of Vision Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Eye such as**
(a) Glaucoma
(b) Infectious ophthalmic diseases - 3hrs

Books and references
Suggested topics for assignment
Pharmacy Practice - III

Scope:
Practicing pharmacists have opportunity to provide various patient care services to improve the patient’s health in community settings through counseling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and providing all hospital pharmacy services including clinical pharmacy services such as drug information and Pharmacovigilance.

Objectives:
Upon completion of the course, the student will be able to
(a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
(b) Understand the professional responsibilities of the pharmacists.
(c) Provide the intended services.

Course duration:

Learning
40 hours of learning by blending teaching. Blending teaching includes didactic and onsite learning.

Assignments
Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and Lecture wise program

1. **Drugs and Poison Information - 06 hrs**
   (a) Introduction to drug information resources available
   (b) Systematic approach in answering DI queries
   (c) Critical evaluation of drug information and literature
   (d) Preparation of written and verbal reports
   (e) Establishing a Drug Information Centre
   (f) Poisons information- organization & information resources
   (g) Drug Information Bulletin

2. **Pharmacovigilance - 05 hrs**
   (a) Scope, definition and aims of Pharmacovigilance
   (b) Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   (c) Reporting, evaluation, monitoring, preventing & management of ADRs
   (d) Role of pharmacist in management of ADR.

3. **Medication Errors**
   Classification, consequences, prevention, and role of Pharmacist. Dispensing errors, and ways to minimize them. - **03 hrs**

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4. **Medication adherence**
Consequences on non-adherence, role of pharmacist methods to improve adherence, compliance aids - **03 hrs**

5. **Communication skills – verbal, written, Body language** - **03 hrs**

6. **OTC medications**
Definition, need, and role of Pharmacist. OTC medications in India, counseling for OTC products. Self medication and role of pharmacist in promoting safe self-medication. - **02 hours**

7. **Responding to symptoms/minor ailments** - **10 hrs**
Relevant pathophysiology, common non-pharmacological and OTC drug therapy, and referral to doctor – in : Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Worm infestations, Pyrexia, Ophthalmic symptoms, URT infections, skin disorders, oral and dental disorders.

8. **Hospital supplies** – **7 hrs**
(a) Surgical items/supplies – catheters, syringes & needles, i.v. sets, Ryle’s tubes, Study of Wound management, stoma and incontinence products, Surgical dressing like cotton, gauze, bandages and adhesive tapes,
(b) sutures, ligatures,
(c) patient care equipment – nebulizers, thermometers, .

9. **Veterinary Pharmacy**
Introduction and Role of pharmacist in procurement and distribution of veterinary medicines - **4 hrs**

Books and references
Suggested topics for assignments
Pharmacy Practice - IV

Scope:
Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in community settings through counseling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and providing all hospital pharmacy services including clinical pharmacy services such as drug information and Pharmacovigilance.

Objectives:

Upon completion of the course, the student will be able to
(a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
(b) Understand the professional responsibilities of the pharmacists.
(c) Provide the intended services.

Course duration:

Learning
40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and lecture wise program

1. Health Accessories - - 05 Hrs
Study and handling of various common health accessories handled in hospital and community pharmacy. Student should have working knowledge, uses and cautions in using these. (Wheel Chairs, Canes, Crutches, and other orthopedic aids, Bed Pans, Vaporizers, Syringes and Needles, Hot water Bottles, Clinical Thermometers, Trusses, First Aid Supplies, Family Medicine Cabinet, etc.

2. Medical gases
Different gases and their use, coding and care of cylinders, delivery of gases to various parts of hospital, domiciliary oxygen services, and role of pharmacist. - 3 hrs

3. I.V admixture services and role of Pharmacist - 3 hrs

4. Total Parenteral Nutrition – Definition, composition and clinical use of TPN 2 hrs

5. Clinical Research - 12 hrs
(a) Introduction to Clinical trials
(b) Various phases of clinical trial.
(c) Methods of post marketing surveillance
(d) Abbreviated New Drug Application submission
(e) Good Clinical Practice – ICH, GCP,
(f) Central drug standard control organisation (CDSCO) guidelines, Schedule Y
(g) Composition, responsibilities, procedures of IRB / IEC
(h) Role and responsibilities of clinical trial personnel as per ICH GC
   (i) Sponsor
   (ii) Investigators
   (iii) Clinical research associate
   (iv) Auditors
   (v) Contract research coordinators
   (vi) Regulatory authority
   (vii) Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment) Informed consent Process

6. Introduction to Biostatistics - 3hrs

7. Research in pharmacy practice areas.

8. Continuing education for pharmacists - 1 hr

9. Compounding of Pharmaceuticals in the hospital/community pharmacy. Weights and measures, calculations involving percentage solutions, allegation, proof spirit, Isotonic solutions. Bulk compounding in hospitals, pre-packaging. - 3Hr

10. Manufacturing of Pharmaceutical Formulations in hospital – various aspects, current status - 03 hrs

11. Radiopharmaceuticals – Handling and Packaging, clinical usage, and role of pharmacist - 02 hrs

12. Applications of IT and computers in pharmacy practice - 2 hrs

13. Provision of cytotoxic chemotherapy, and various considerations/handling. Handling of cytotoxic waste and disposal. Pharmaceutical (Medicines and allied products) waste management in hospitals, community pharmacy, and the community and the role of the pharmacist. - 3Hr

14. Medical Devices & I.V. pumps

15. Individualised medicines, Gene therapy, Genomics & proteomics, Biochips, biosensors and MEMS micro electro mechanical systems - 2 Hr
Pharmaceutical Jurisprudence

Scope:
A profession becomes successful when it is guided with suitable laws. This course describes about the Pharmacy Act, Drugs and Cosmetics Act, Dangerous drugs act, Medicinal and Toilet preparation act, DPCO and Professional ethics.

Course Objectives:

Upon completion of the course the student shall be able to
(a) Understand various concepts of the pharmaceutical legislation in India
(b) Know various rules drafted in Drug and Cosmetic Act, Pharmacy Act, NDPS Acts, relevant to pharmacy practice.
(c) Know the Consumer Protection Act, PFA Act, DPCO,
(d) Understand the labeling requirements and packaging guidelines for drugs and cosmetics

Course duration:

Learning
40 hours of learning by blended teaching. Blended teaching method includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and Lecture wise Program

1. A brief review of Pharmaceutical legislations - 01 hr
A Study of various pharmaceutical and related legislations with more emphasis on aspects relevant to community & hospital pharmacy practice in India. Study the aspects only from practical angle, with examples, case studies, etc:

2. Drugs and Cosmetics Act-1940 and Rules 1945 - 15 hrs
(a) Duties & Responsibilities of Drug Inspectors, other officers, and obligations of the pharmacy to them
(b) Brief about DTAB, DCC, Drug testing laboratories
(c) Various drug licences for retail pharmacy, requirements to start a pharmacy/medical store, application forms, issue of licence, display of licences, duration of licences, laws related to stocking, handling and sale of drugs and devices
(d) Various schedules under the Act & Rule – study in brief –those relevant to pharmacy practice
(e) Labelling requirements of drugs – various aspects
(f) Spurious, misbranded, adulterated, counterfeit drugs – various aspects related to this, how to recognize, role of the pharmacist
(g) Import of drugs for personal use
(h) Various documents to be maintained under the Act & Rules by a pharmacy
(i) Storage requirements, handling expired goods
(j) Various punishments under the Act
(k) Practical study of Prescription and non-prescription drugs, market samples, examine for labeling, etc.
(l) Laws relating to various traditional systems/medicines approved in India
(m) Banning of drugs

3. Pharmacy Act – 1948 - 03 hrs
5. Narcotic Drugs and Psychotropic Substances Act – 1985 - 04 hrs
6. Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules, 1954 - 02 hrs
7. Essential Commodities Act - 02 hrs
8. Drugs Prices Control Order - 02 hrs.
10. Consumer Protection Act, 1986 - 02 hrs
11. Prevention of Food Adulteration Act & Rules, laws relating to Dietary Supplements, Food supplements, etc - 02 Hrs
12. The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 2003 - 02 Hrs

Books and references
Social Pharmacy - II

Scope:
Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in the society. By monitoring the health of the individuals, providing them education about health, precautions, and pharmacists can improve their professional image.

Objectives:

Upon completion of the course, the student will be able to
(a) Understand the social responsibility of the pharmacists in the society
(b) Provide professional services to the patients.

Course duration:

Learning
40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments
Each student should complete two assignments covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Syllabus and lecture wise programme

1. Preventive care:
   (a) Vaccines, and immunizations – and Role of Pharmacist & 2 hours
   (b) Role of Pharmacist in Demography & Family Planning - 2 hours
   (c) Mother and child health, importance of breastfeeding, ill effects of formula foods and bottle feeding, and role of Pharmacist - 4 hours
   (d) Geriatrics and role of Pharmacist - 1 hour
   (e) Effect of Environment on Health & Role of Pharmacist – Water pollution, safe supply of water, 1 hour
   (f) Occupational diseases/illnesses and Role of Pharmacist - 1 hours
   (g) Mental Health and role of Pharmacist - 1 hours
   (h) Psychosocial Pharmacy : Drugs of misuse and abuse – psychotropic and narcotics, and other pharmaceuticals and chemicals, tobacco and tobacco products, alcohol. Social & psychosocial impact of these, role of pharmacist in reducing, preventing the menace.
   Tobacco cessation and role of pharmacist - 3 Hr
   (i) Palliative/terminal care and role of pharmacist in handling psychosocial issues - 3Hr
   (j) Care for disabled and role of pharmacist in handling psychosocial issues - 2 Hr
   (k) Early intervention in hereditary diseases, screening tests - 1 hour

2. Nutrition and health : - 20 Hr
   (a) Basics of nutrition – Macronutrients and Micronutrients, fibre – importance, sources (Plant and animal origin),
   (b) Calorific and nutritive values of various foods
(c) Daily/recommended dietary allowance and functions of each. Balanced diets – for various individual groups. Nutrition deficiency diseases
(d) Food as a medicine. Brief study of various concepts of Naturopathy.
(e) Nutrition as per Ayurveda – Ayurvedic outlook to diets – as per prakruti, seasons, seasonal availability of foods, etc. Prakruti study in brief.
(f) Wrong/improper foods and food habits, causes of various disease conditions, ill effects of wrong foods/fast foods, timed foods, etc – Western foods as well as Indian foods – reasons for wrong effects on body.
(g) Basics of genetically modified foods – advantages, disadvantages
(h) Effects of environment on foods, artificial ripening, hybridization, use of pesticides, adulteration, etc.
(i) Nutrition/dietary recommendation for different disease conditions – e.g. diabetes, blood pressure, Hyperlipidemia, arthritis, renal disease, liver disease, allergies, etc.
(j) Artificial sweeteners, zero calorie concept, glycemic index of foods
(k) Dietary supplements, neutriceuticals, food supplements – legal standing, indications, rational use, benefits, ADRs, Drug Interactions, pharmacoeconomics.

3. First Aid Services in Community Pharmacy - 10 hours

RECOMMENDED BOOKS
1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone Publication
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
5. Text Book of Hospital Pharmacy by Quadry and Merchant.
7. Text Book of Community Pharmacy Practice. RPSGB Publication.
9. Community Pharmacy: Symptoms, Diagnosis and Treatment: Paul Rutter
10. Minor Illness in Major Diseases-the Clinical Manifestation in the Community: Paul Stillman
11. Sociology for Pharmacist: Tayler, Nettleton, Harding
12. Pharmacy Practice: Tayler, Harding
13. Social Pharmacy: Tayler, Geoffery
14. Stockley’s Drugs Interaction: Karen Baxter
15. Cooper and Gunn : Dispensing for Pharmacy Students.
17. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
18. Remington’s Pharmaceutical Sciences
20. Biopharmaceutics by Swarbrik
25. Various Reports of the Pharmaceutical Enquiry Committee
27. Various Reports of Amendments.
30. Drug Information About Commonly Used Drugs: P.P.Sharma, R.Sing
Course of study.
The course of study shall consist of the subjects as given in the Tables below. The course shall consist of class room teaching and assignment works. The assignment works shall be done at the place of work under the supervision and guidance of teaching staff of the academic institution. The number of contact hours in a week devoted to each subject for class room teaching shall not be less than that noted against it in columns (3) below.

<table>
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<tr>
<th>S. No</th>
<th>Name of Subject</th>
<th>Minimum No. of total contact hours</th>
<th>No. of contact hours /week</th>
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<td>Case presentation, Seminar, Assignments</td>
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**FIRST YEAR**

**Second Year**

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