### <u>Course curriculum</u> Bachelor of Pharmacy (Practice) [B. Pharm. (Practice)] BRIDGE COURSE

### 1.1. Pathophysiology and Pharmacotherapeutics -I

#### 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

### 1.2. Pathophysiology and Pharmacotherapeutics- II

# 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

(a) Erythropoietic system – Over view, Iron deficiency anemia, Megaloblastic anemia, Sideroblastic anemia, Hemolytic anemia, Venous Thromboembolism, Arterial Thromboembolism, Drug induced blood disorders.

### 1.3. Pharmacy Practice I

**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.

b) Advantages, need and disadvantages/risks of Hospitalization. Nosocomial infections/HAI – worldwide scenario, statistics/prevalence, dangers, precautions to take. Problems related to hospitals, high risk environment.

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.

### 1.4. Pharmacy Practice II

### 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.
e. PPIs – (Patient Package Insert) - Basic concept, Importance and beneficial use of PPIs. Scenario in India and other countries.

### 5. Pharmaceutical Care - 02 hours

Definition, principles and procedures of pharmaceutical care

### 6. Patient Counseling - 04 hours

46 THE GAZETTE OF INDIA : EXTRAORDINARY [PART III—SEC. 4] 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

### **1.5. Applied Pharmaceutics**

### 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
- a) Definition and applications of prodrugs
- 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

### <u> 1.6 Social Pharmacy – I</u>

### 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 pharmacoeconomic 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

a) Epidemiology of Communicable Diseases : Causative agents and Clinical presentations and Role of Pharmacist in prevention of communicable diseases :

(i) Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis

(ii) Intestinal infections – poliomyelitis, viral hepatitis, cholera, acute diarrhoeal diseases, typhoid, food poisoning, amebiasis, worm infestations

(iii) Arthropod-borne infections - dengue, malaria, filariasis and, chikungunya

(iv) Zoonoses – rabies, yellow fever, Japanese encephalitis, plague, human salmonellosis, ricketsial diseases, taeniasis, hydatid disease, leishmaniasis

(v) Surface infections - trachoma, tetanus, leprosy, STDs, HIV/AIDS

(vi) Emerging and reemerging infectious diseases.

### 2nd Year

### 2.1 Pathophysiology and Pharmacotherapeutics III

### 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, Gonarrhoea and Syphillis

### 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
Books and references
Suggested topics for assignment.

### 2.2. Pathophysiology and Pharmacotherapeutics IV :

### 1. Oncology: - 15 Hrs

Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy induced nausea and emesis

### 2. Dermatology: - 7 Hrs

(a) 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

### 2.3. Pharmacy Practice III

### 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
 52 THE GAZETTE OF INDIA : EXTRAORDINARY [PART III—SEC. 4]

**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

### 2.4. Pharmacy Practice IV

### 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 admixure services and role of Pharmacist - 3 hrs

4. Total Parenteral Nutrition – Definition, composition and clinical use of TPN 2 hrs 5. Clinical Reseach - 12 hrs Introduction to Clinical trials Various phases of clinical trial. Methods of post marketing surveillance Abbreviated New Drug Application submission Good Clinical Practice – ICH, GCP, - Central drug standard control organisation (CDSCO) guidelines, Schedule Y -Composition, responsibilities, procedures of IRB / IEC Role and responsibilities of clinical trial personnel as per ICH GC a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority 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.** Compunding 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

## 2.5. Pharmaceutical Jurisprudence

### 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

• Duties & Responsibilities of Drug Inspectors, other officers, and obligations of the pharmacy to them

• Brief about DTAB, DCC, Drug testing laboratories

• 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

- Various schedules under the Act & Rule study in brief –those relevant to pharmacy practice
- Labelling requirements of drugs various aspects
- Spurious, misbranded, adulterated, counterfeit drugs various aspects related to this, how to recognize, role of the pharmacist
- Import of drugs for personal use
- Various documents to be maintained under the Act & Rules by a pharmacy
- Storage requirements, handling expired goods
- Various punishments under the Act

• Practical study of Prescription and non-prescription drugs, market samples, examine for labeling, etc.

<sup>1</sup>Hkkx IIIµ[k.M 4º Hkkjr dk jkti=k % vlk/kj.k 55

- Laws relating to various traditional systems/ medicines approved in India
- Banning of drugs
- 3. Pharmacy Act 1948 03 hrs
- 4. Medicinal and Toilet Preparation Act-1955 04 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 02hrs.
- 9. Prevention of Cruelty to Animals Act, 1960 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** 

## 2.6. Social Pharmacy II

### Syllabus and lecture wise programme

### A. Preventive care:

1. Vaccines, and immunizations – and Role of Pharmacist & 2 hours

2. Role of Pharmacist in Demography & Family Planning - 2 hours

3. Mother and child health, importance of breastfeeding, ill effects of formula foods and bottle feeding,

and role of Pharmacist - 4 hours

4. Geriatrics and role of Pharmacist - 1 hour

5. Effect of Environment on Health & Role of Pharmacist – Water pollution, safe supply of water,1 hour

6. Occupational diseases/illnesses and Role of Pharmacist - 1 hours

7. Mental Health and role of Pharmacist - 1 hours

8. 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

9. Palliative/terminal care and role of pharmacist in handling psychosocial issues - 3Hr

10. Care for disabled and role of pharmacist in handling psychosocial issues - 2 Hr

11. Early intervention in hereditary diaseses, screening tests - 1 hour

### B. Nutrition and health : - 20 Hr

1. Basics of nutrition – Macronutrients and Micronutrients, fibre – importance, sources (Plant and animal origin),

2. Calorific and nutritive values of various foods

3. Daily/recommended dietary allowance and functions of each. Balanced diets – for various individual groups. Nutrition deficiency diseases

4. Food as a medicine. Brief study of various concepts of Naturopathy.

5. Nutrition as per Ayurveda – Ayurvedic outlook to diets – as per prakruti, seasons, seasonal availability of foods, etc. Prakruti study in brief.

6. 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.

7. Basics of genetically modified foods – advantages, disadvantages

 8. Effects of environment on foods, artificial ripening, hybridization, use of pesticides, adulteration, etc.
 9. Nutrition/dietary recommendation for different disease conditions – e.g. diabetes, blood pressure, Hyperlipidemia, arthritis, renal disease, liver disease, allergies, etc.

10. Artificial sweeteners, zero calorie concept, glycemic index of foods

11. Dietary supplements, neutraceuticals, food supplements – legal standing, indications, rational use, benefits, ADRs, Drug Interactions, pharmacoeconomics.

### C. First Aid Services in Community Pharmacy - 10 hours