

Pharmaceutics -IX (Dosage Form Design)

Theory

1. Preformulation studies:
 - a) Study of physical properties of drug like physical form, particle size, shape, density, wetting dielectric constant. Solubility, dissolution and organoleptic property and their effect on formulation, stability and bioavailability.
 - b) Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc., and their influence on formulation and stability of products.
 - c) Study of pro-drugs in solving problems related to stability, bioavailability and elegance of formulations.
2. Design, development and process validation methods for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions.
3. Stabilization and stability testing protocol for various pharmaceutical products.
4. Performance evaluation methods
 - a) In-vitro dissolution studies for solid dosage forms methods, interpretation of dissolution data.
 - b) Bioavailability studies and bioavailability testing protocol and procedures.
 - c) In-vivo methods of evaluation and statistical treatment.
5. GMP and quality assurance, Quality audit
6. Design, development, production and evaluation of controlled released formulations.

Practical

1. Preformulation studies including drug-excipient compatibility studies, effect of stabilizers, preservatives etc. in dosage form design.
2. Experiments demonstrating improvement in bioavailability through prodrug concept.
3. Stability evaluation of various dosage forms and their expiration dating.
4. Dissolution testing and data evaluation for oral solid dosage forms.
6. In-vivo bioavailability evaluation from plasma drug concentration and urinary excretion curves.
7. Design, development and evaluation of controlled release formulations.

Pharmaceutical Management and Entrepreneurship

THEORY

1. Concept of Management: Administrative Management (Planning, Organizing, Staffing, Directing and Controlling), Entrepreneurship development, Operative Management (Personnel, Materials, Production, Financial, Marketing, Time/space, Margin/Morale). Principles of Management (Co-ordination, Communication, Motivation, Decision-making, leadership, Innovation, Creativity, Delegation of Authority / Responsibility, Record Keeping). Identification of key points to give maximum thrust for development and perfection.
2. Accountancy: Principles of Accountancy, Ledger posting and book entries, preparation of trial balance, columns of a cash book, Bank reconciliation statement, rectification of errors, Profits and loss account, balance sheet, purchase, keeping and pricing of stocks, treatment of cheques, bills of exchange, promissory notes and hundies, documentary bills.
3. Economics: Principles of economics with special reference to the laws of demand and supply, demand schedule, demand curves, labor welfare, general principles of insurance and inland and foreign trade, procedure of exporting and importing goods.
4. Pharmaceutical Marketing: Functions, buying, selling, transportation, storage, finance, feedback, information, channels of distribution, wholesale, retail, multiple shop and mail order business.
5. Salesmanship: Principles of sales promotion, advertising, ethics of sales, merchandising, literature, detailing. Recruitment, training and evaluation.
6. Market Research:: Measuring & Forecasting Market Demands-Major concept in demand measurement, Estimating current demand, Geodemographic analysis, Estimating industry sales, Market share & Future demand.
7. Market Segmentation & Market Targeting.
8. Materials Management: A brief exposure or basic principles of materials management-major areas, scope, purchase, stores, inventory control and evaluation of materials management.
9. Production Management: A brief exposure of the different aspects of Production Management-Visible and Invisible inputs, Methodology of Activities, Performance Evaluation Technique, Process-Flow, Process Know how, Maintenance Management.

Practical

Conduct a survey on techno-economic study and formulate a project plan to establish a pharmaceutical industry

Engineering Drawing

Practical

1. Isometric and orthographic projections
2. Basic Engineering Drawing Practice - Bolts, nuts, rivetted fronts, screws, worm screws as per specification.
3. Drawing of simple pharmaceutical machinery parts.
4. Layout designing of pharmaceutical production units, retail shops and wholesale

Pharmacology - III

Theory

I. Drugs Acting on the Gastrointestinal Tract:

- (a) Antacids, Anti Secretory and Anti-ulcer drugs.
- (b) Laxatives and antidiarrhoeal drugs.
- (c) Appetite Stimulants and Suppressants
- (d) Emetics and anti-emetics.
- (e) Miscellaneous-Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.

2. Pharmacology of Endocrine System:

- (a) Hypothalamic and pituitary hormones
- (b) Thyroid hormones and anti thyroid drugs, parathormone, calcitonin and Vitamin D.
- (c) Insulin, oral hypoglycaemic agents & glucagon.
- (d) ACTH and corticosteroids.
- (e) Androgens and anabolic steroids.
- (f) Estrogens, progesterone and oral contraceptives.
- (g) Drugs acting on the uterus.

3. Chemotherapy:

- (a) General Principles of Chemotherapy.
- (b) Sulfonamides and cotrimoxazole.
- (c) Antibiotics-Penicillins, Cephalosporins, Chloramphenicol Erythromycin, Quinolones and Miscellaneous Antibiotics.
- (d) Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases.
- (e) Chemotherapy of malignancy and Immunosuppressive Agents.

4. Principles of Toxicology:

- (a) Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates, opioids, organophosphorous and atropine poisoning.
- (b) Heavy metals and heavy metal antagonists.

Practical

1. Experiments on Isolated Preparations:

- To calculate the pA₂ value of atropine using acetylcholine as an agonist on rat ileum preparation.

2. Pharmacology of the Gastrointestinal Tract:

- To study the Anti- secretory and anti-ulcer activity using pylorus ligated rats.

3. To determine the effects of certain clinically useful drugs on human volunteers like:

- Antihistaminics
- Anti-anxiety and sedative drugs
- Analgesics
- Beta blockers.
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1. Basic Concepts of Pharmacotherapy.
2. Important Disorders of Organ Systems and their Management:
 - a. Cardiovascular Disorders-Hypertension, Congestive Heart Failure, Angina, Acute Myocardial Infarction, Cardiac arrhythmias.
 - b. CNS Disorders: Epilepsy, Parkinsonism, Schizophrenia, Depression.
 - c. Respiratory Disease-Asthma, COPD.
 - d. Gastrointestinal Disorders-Peptic ulcer, Ulcerative colitis, Hepatitis, Cirrhosis.
 - e. Endocrine Disorders-Diabetes mellitus and Thyroid Disorders.
 - f. Infectious Diseases-Tuberculosis, Urinary Tract Infection, Enteric Infections, Upper Respiratory Infections.
 - g. Hemopoietic Disorders-Anemias.
 - h. Joint and Connective Tissue Disorders-Rheumatic Diseases, Gout and Hyperuricemia.
 - i. Neoplastic Diseases- Acute Leukaemias, Hodgkin's disease.

Research Methodology & Project Design

1. Introduction, meaning and nature of research, scope and objective of research, type of researches, health research and its benefits.
2. Review of literature, need, source and reviewing in bibliography
3. Research design, its purpose, characteristics, types of research design, survey method, pre testing, pilot study and common sources of errors in research design
4. Measurement and scaling, variables
5. Data collection and data collection tools, data management
6. Sampling theory and methods of sampling and types
7. Data analysis: editing, coding, tabulation and types of tables, graphical and diagrammatic presentation
8. Statistical tools for data analysis
9. Topic selection, defining objective and research question, research hypothesis
10. Research report writing, types of report, draft report and presentation and dissemination plan
11. Health research, policy and priorities, pharmaceutical researches, indicators in health researches, pharmaceutical researches, laboratory and survey research

Practical

Write a project proposal for 8th semester project work and conduct literature survey.

SEMESTER VIII

Clinical Pharmacy an Drug Interaction

1. Introduction to Clinical Pharmacy.
2. Clinical Pharmacokinetics and individualization of Drug Therapy.
3. Drug Delivery Systems and their Biopharmaceutic & Therapeutic Considerations.
4. Drug Use During Infancy and in the Elderly (Pediatrics & Geriatrics).
5. Drug use during Pregnancy.
6. Drug induced Diseases.
7. The Basics of Drug Interactions.
8. General Principles of Clinical Toxicology.
9. Interpretation of Clinical Laboratory Tests.
10. Total Parenteral Nutritions
11. Therapeutic Drug Monitoring
12. Essential Drugs (concept, benefit and criteria for selection), Essential drug list of Nepal. Standard Treatment Schedule (concept, criteria and benefits) Standard Treatment Schedule of Nepal. Rational Drug Use (concept, WHO guidelines), Rational Drug Situation in Nepal.
13. Clinical trial and its national and international provisions

Practical

Case studies and their presentation

Hospital Pharmacy

THEORY

1. Organization and Structure: Organization of a hospital and hospital pharmacy, Responsibilities of a hospital pharmacist, Pharmacy and therapeutic committee, Budget preparation and Implementation.
2. Hospital Formulary: Contents, preparation and revision of hospital formulary.
3. Drug Store Management and Inventory Control:
 - a. Organization of drug store, Types of materials stocked, storage conditions.
 - b. Purchase and Inventory Control principles, purchase procedures, Purchase order, Procurement and stocking.
4. Drug distribution Systems in Hospitals:
 - a. Out-patient dispensing, methods adopted.
 - b. Dispensing of drugs to in-patients. Types of drug distribution systems. Charging policy, labeling.
 - c. Dispensing of drugs to ambulatory patients.
 - d. Dispensing of controlled drugs.
5. Central Sterile Supply Unit and their Management: Types of materials for sterilization, packing of materials prior to sterilization, sterilization equipments, Supply of sterile materials.
6. Manufacture of Sterile and Nonsterile Products: Policy making of manufacturable items, demand and costing, personnel requirements, manufacturing practice, Master formula Card, production control, manufacturing records.
7. Drug Information Services: Sources' of Information on drugs, disease, treatment schedules, procurement of information, Computerized services (e.g., MEDLINE), Retrieval of information, Medication error.
8. Records and Reports: Prescription filling, drug profile, patient medication profile, cases on drug interaction and adverse reactions, idiosyncratic cases etc.
9. Nuclear Pharmacy: Introduction to Radio- pharmaceuticals, radio-active half life, Units of radio-activity Production of radio-pharmaceuticals, methods of isotopic tagging, preparation of radio-isotopes in laboratory using radiation dosimetry, radio-isotope generators, Permissible radiation dose level, Radiation hazards and their prevention, specifications for radio-active laboratory.

Hospital Pharmacy Lab

1. Experiments based on sterilization of various types of materials used in Hospitals.
2. Practical designed on the use of computers in Drug Information Centre, prescription filling, documentation of information on drug interaction.

Social Pharmacy & Pharmaceutical jurisprudence

THEORY

Social Pharmacy

1. Profession & professionalism, pharmacy as profession, social and behavioral aspects of pharmacy, contribution of pharmacy to today's health care provision
2. Communication Skills: Explain nonverbal communication, patterns of behavior in communication, questioning and listening skill, barriers of communication, confidentiality
3. *Concept of pharmacoeconomics, selection and choice of medicines based on -cost effectiveness, cost benefit and cost minimization approach.*
4. *Concept of quality, subjective and objective quality, quality assurance of health care provision, quality system and management, total quality management, quality of drug provision, theory and concept of technology assessment, health care technology assessment in improving quality of care, economic aspects of quality, quality in terms of rational drug uses*
5. Market failure in pharmaceuticals in pharmacotherapy. market agency relationship
6. Opportunity cost in pharmacy, mortality morbidity, DALY QUALY , Concept of health for all, millennium development goal, strategic planning,
7. Theory and indicators for monitoring and evaluation health care project, need based and right based activities
8. Need based and right based approach in health care, theory and process of community awareness in utilizing health care services.
9. Health insurance, drug schemes, community mobilization through participatory approach

Pharmaceutical Jurisprudence

1. History of pharmaceutical legislation, Pharmaceutical industry and pharmaceutical education.
2. An elaborate study of the following
 - Drugs Act, 1978
 - Drug Registration Regulation
 - Drug Consultative Council and Drug Advisory Regulations
 - Drug Standard Regulation
 - Drug Inspection Regulation
 - Drug Manufacturing Codes
 - Good Manufacturing Practices
 - Drugs Sale and Distribution Codes
 - Pharmacy Council Act
3. A brief account on the following
 - Regulatory provisions for veterinary, ayurvedic and other system of medicines
 - Company Act of Nepal
 - Patents Act 1970.

- National Health Research Council Act
- Professional councils
- Consumer protection act
- Narcotic drugs control act relating to pharmaceutical product and the relation of act with Drugs Act, 1978
- Control of poisonous & hazardous chemical substances and their control mechanism
- Pharmacy institutions and organizations of Nepal and their functions
- Drugs banned in Nepal and the reason of drug banning
- A brief account about the Drug & Cosmetic Act of India, UK and USA

Quality Assurance and Instrumental Analysis

THEORY

A. Quality assurance

1. GMP, GLP, ISO 9000, TQM, Quality Review and Quality Documentation.
2. Regulatory control, regulatory drug analysis, interpretation of analytical data.
3. Validation, quality audit: quality of equipment, validation of equipment, validation of analytical procedures.

B. The theoretical aspects, basic instrumentation, elements of interpretation of spectra, and applications of the following analytical techniques should be discussed:

1. Ultraviolet and visible spectrophotometry
2. Fluorimetry.
3. Infrared spectrophotometry.
4. Nuclear Magnetic Resonance spectroscopy including ¹³C NMR.
5. Mass Spectrometry.
6. Flame Photometry.
7. Emission Spectroscopy.
8. Atomic Absorption Spectroscopy.
9. X-ray Diffraction.
10. Radio immunoassay.

Quality Assurance and Instrumental Analysis Lab

1. Quantitative estimation of at least ten formulations containing single drug or more than one drug, using instrumental techniques.
2. Estimation of Na, K, Ca ions using flame photometry.
3. Workshop to interpret the structure of simple organic compounds using UV, ¹³C NMR and MS.

PROJECT WORK

The project work includes literature survey, laboratory experiment/field work, seminar, project report, presentation and viva.

Note: The course will be followed by a two months industry/hospital/laboratory internship.