SEVENTH SEMESTER

PHAR 411 Dosage Form Design [45 hours]

Unit- 1. Preformulation studies: (13 hours)

a) Introduction, goals of preformulation, Study of physical properties of drug and their effect on formulation, stability and bioavailability.

- **Bulk characterization**:-Crystallinity and polymorphism, hygroscopicity, Fine particle characterization, Bulk density and study of powder flow properties (Carr's index, Hausner index, Angle of Repose).
- **Solubility Analysis:** Ionization constant –pKa; pH solubility profile and common ion effect –Ksp; effect of temperature; Solubilisation; Partition Coefficient and dissolution.
- **Stability Analysis:** Stability in toxicology formulation; Solution stability; PH rate profile ; solid state stability; bulk stability ; compatibility studies with excipient.

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 elegancy of formulations.

- Rationale for prodrug formation, potential prodrug candidates, Design and bioactivation, classification of prodrug (carrier linked prodrug, metabolic prodrug), pharmaceutical application of prodrug (Improvement of taste, odour, reduction of GI irritation, reduction of pain at site of injection, enhancement of solubility and dissolution of drug, chemical stability, prolonged duration of action, site specific drug delivery)

Unit 2: Design, development and process validation methods for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions**. (5 hours)**

- Introduction to validation, importance of validation, process validation, types of process validation (Prospective, Concurrent, Retrospective and Revalidation), validation team responsibility, elements of validation (DQ, IQ, OQ and PQ)
- Process validation: Process validation activities (process design, process qualification and verification), change control, phases of process validation (Pre-Validation Phase or the Qualification Phase, Process Validation Phase, Process Qualification phase and Validation Maintenance Phase); Required Validation Documents: validation master plan (VMP), Validation protocol (VP), Validation report (VR) and Standard Operating procedure (SOP).
- Process validation method of solid dosage form (Tablet): Process overview of tablet manufacturing process, validation of process parameters in tablet manufacturing

(Focus on process critical parameters of process stages of dry mixing, granulation, wet milling, drying, dry milling, lubrication, compression, coating and packing)

- Process validation method of suspension dosage form: Process overview; validation of process parameters of suspension manufacturing (mixing, size reduction, filling)

Unit-3. Stabilization and stability testing protocol for various pharmaceutical products (6 hours)

- Brief introduction of rate kinetics and methods of determination of shelf
- Protection against hydrolysis, oxidation and photochemical degradation.
- Stability testing: Accelerated analysis for chemical stability and limitation (Arrhenius plot)
- Stability testing protocol: ICH guidelines for storage conditions, concept of climatic zone as per ICH, stress testing, accelerated and long term stability testing and on-going testing (focus on drug substance and drug product).
- DDA guidelines for stability testing 2007

Unit 4. Performance evaluation methods (6 hours)

a) **In-vitro dissolution studies for solid dosage forms methods, interpretation of dissolution data:** Introduction, Noyes Whitney equation, factors affecting dissolution rate relating to the solid dosage form (effect of formulation factors and effect of processing factors), basic knowledge about dissolution apparatus (USP apparatus I and II).

b) **Bioavailability studies and bioavailability testing protocol and procedures:** Bioavailability and bioequivalence, purpose of bioavailability studies, relative and absolute bioavailability, Methods of assessing bioavailability (Pharmacokinetic methods and pharmacodynamic methods).

Pharmacokinetics methods: Plasma data (t_{max}, C_{max}, AUC), urine data

pharmacodynamic methods: Acute pharmacological effect and clinical response.

c) In-vivo methods of evaluation and statistical treatment:

Unit 5. GMP and quality assurance, Quality audit **(5 hours)**

- GMP – Introduction, Relationship among Quality Elements (Quality Assurance, Good Manufacturing Practices (GMP) for Drugs and Quality control). Short description of Premises, Personnel and equipments. GMP regulation in Nepal including *"Ausadi Utpadan Samhita".*
- Quality Audit (Types: 3rd Party Audit, 2nd Party Audit, 1st Party Audits, Audit Categories: System Audit, Conformance Audit, Compliance Audit, Process Audit, Product Audit and Department Audit. Benefits of audit). Site Master File, GMP certification: Audit of Hardware, software and Practice.
- Quality Assurance: Concept, function and organizational Approach.

Unit 6. Design, development, production and evaluation of controlled released formulations (10 hours)

- Introduction to CR/SR preparations, concept of controlled release formulation, challenges of CR drug delivery system, advantages and disadvantages, Factors influencing the design and performance of CR products (**physiochemical properties**: molecular size and diffusivity, aqueous solubility, ionization constant, partition coefficient, stability, **pharmacokinetic and pharmacodynamic considerations**: release rate and dose, **Biological factors**: Absorption, distribution, metabolism and elimination half life, therapeutic index, duration of action.
- Kinetics of drug release from CRDS: Zero order, first order, Hixson-Crowell Release Model, Higuchi Release Model and Korsmeyer-Peppas Release Model
- Oral controlled release systems: Dissolution controlled release (Matrix and encapsulated dissolution), diffusion controlled release (Reservoir and matrix system), dissolution and diffusion controlled release, Osmotically controlled release, pH independent formulations, Ion exchange resins.
- Evaluation of CR formulations: Quality control methods(Identity, purity, strength, stability of the dosage form and drug in the dosage form, disintegration and dissolution, dosage form appearance, bioavailability of the drug from dosage form.

PHAR 411 Lab Dosage Form Design 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.

Books and Other Resources Suggested

1. N.K. Jain , Controlled and Novel drug delivery., CBS Publishers and distributors. New Delhi.
2. Leon Lachman ,Theory and Practice of Industrial Pharmacy , Varghese publishing house, 3rd edition.
3. Remington's, The Sciences and practice of pharmacy- Volume I, II., Lippincott Williams and Wilkins London, 20th edition.
4. Hillery and loyed, Drug delivery and targeting., Tylor and franicis London. 1st edition.
5. Yie W. Chien, Novel drug delivery systems., Mareel Dekker Inc.

6. Ansel, Howard, Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams and Wilkins London, 7th edition.
7. Hamed M. Abelon, Dissolution, Bioavailability and Bioequivalence, Mack Publishing Company, Pennsylvania.

PHAR 412 Pharmaceutical Management [45 hours]

Unit-1: Concept of Management (12 hours)
Administrative Management (Planning, Organizing, Staffing Directing and Controlling). Entrepreneurship development, Operative Management (Personnel, Materials, Production, Financial, Marketing, Time/space, Margin/ Morale) Principles of Management (Coordination, 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. Total Quality Management (TQM).

Unit-2: Pharmaceutical Marketing (6 hours)
Functions, buying, selling, transportation, storage financed. Feedback information, channels of distribution, wholesale, retail, department store, multiple shop and mail order business.

Unit-3: Salesmanship and Market Research (6 hours)
Principle of sales promotion, advertising, ethics of sales, merchandising, literature, detailing, Recruitment, training, evaluation, compensation to the pharmacist. Measuring & Forecasting Market Demand - Major concept in demand measurement, Estimating current demand Geo-demo- graphic analysis. Estimating industry sales, Market share and future demand. Market segmentation & Market targeting.

Unit-4: Introduction to Accountancy (5 hours)
Introduction, Accounting Process, Bank Reconciliation, Trail Balance, Profit & Loss Account, Depreciation, Inventory management & Accounting, Long Lived Assets and Long term liabilities.

Unit-5: Material Management (4 hours)
A brief description of basic principles of material management, major areas, scope, purchase, stores, inventory control and evaluation of materials management.

Unit-6: Production Management (6 hours)
A brief description of the different aspects of Production Management. Visible and Invisible inputs, Methodology of Activities Performance Evaluation Technique Process, Flow, Process Know-how, Maintenance Management.

Unit-7: Introduction to Microeconomics (6 hours)

Introduction, Supply/Demand and Elasticity, types of market (Monopoly, Competitive, Oligopoly, and Monopolistic Competition).

BOOKS RECOMMENDED:

1. Beri, Market Researth – Tata Mc Graw Hill
2. Chary S.N, Production and Operative Management / Tata Mc Graw Hill.
3. Datta A.K., Material Management / PHI.
4. Chadwick Leslie, The essence of management accounting / PHI.
5. Massie L. Joseph Essentials of Management / PHI.
6. Barthwal R.R, Industrial Economics –. / New Age International.
7. Shreenivasan K.R., An Introduction to Industrial Management –/ Vikas.
8. Daver Rustam S. Salesmanship and Publicity –/ Vikas.
9. Mukopadhyay Sekhar, Pharmaceutical Selling, Sterling Publishers.
10. Koontz H, Weihrich H, Essentials of Management, Tata Mc Graw Hill.
11. Vidya sagar Pharmaceutical Industrial Management, Pharma Book Syndicate

PHAR 413 Pharmacotherapeutics [45 hrs]

1. Basic Concepts of Pharmacotherapy**.(1 hr)**

2. Important Disorders of Organ Systems and their Management: **(44 hrs)**

2.1. Cardiovascular Disorders – Hypertension, Congestive Heart Failure, Angina, Acute Myocardial Infarction, Cardiac arrhythmias (8hrs)

2.2 .CNS Disorders: Epilepsy, Parkinsonism, Schizophrenia, Depression (7hrs)

2.3 .Respiratory Disease- Asthma, COPD (4hrs)

2.4. Gastrointestinal Disorders-Peptic ulcer, Ulcerative colitis, Hepatitis, Cirrhosis (8hrs)

2.5 Endocrine Disorders-Diabetes mellitus and Thyroid Disorders (3hrs).

2.6 Infectious Diseases-Tuberculosis, Urinary Tract Infection, Enteric Infections, Upper Respiratory Infection (5hrs).

2.7 Hemopoietic Disorders-Anemias (6hrs)

2.8 Joint and Connective Tissue Disorders-Rheumatic Diseases, Gout and Hyperuricaemia (1hrs)

2.9 Neoplastic Diseases- Acute Leukaemias, Hodgkin's diseases (2hrs)

Books and Other Resources Recommended

1. Sathoskar, Pharmacology and pharmacotherapeutics, Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
2. Roger Walker and Cleve Edwards: Clinical Pharmacy and Therapeutics.
3. Current Medical Diagnosis and Treatment(CMDT)
4. Washington Manual and Medical therapeutics, 32nd Edition.
5. Bertram. G. Katzung, Basic and clinical pharmacology
6. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann: The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
7. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences, 20th Edition. Hamsten, Drug interaction, Kven Stockley.
8. Laurence, DR and Bennet PN. Clinical Pharmacology, Scientific book agency
9. Dr. D.R Krishna, V. Klotz, Clinical pharmaco kinetics, Publ Springer Verlab
10. M Rowland and T N Tozer, "Clinical Pharmacokinetics" 2nd ed Lea & Febiger, NY.
11. Grahame smith and Aronson, Clinical pharmacology and drug therapy
12. Richard A Helms, Text Book of Therapeutics Drug and Disease Management Hardbound.
13. Herfindal E T and Hirschman JL, Williams and Wilkins, Clinical Pharmacy and therapeutics
14. Applied Therapeutics, The clinical uses of Drugs applied therapeutics INC

PHAR 414 Research Methodology [45 hours]

1. Introduction, meaning and nature of research, scope and objective of research, type of researches, health research and its benefits. Research Ethics and plagiarism. Health research, policy and priorities, pharmaceutical researches, indicators in health researches, pharmaceutical researches, laboratory and survey research **(4 hrs)**
2. Introduction, significance of valid design **(1hr)**
3. Research design: Observational Study – types, design, example. Interventional study – types, design, example. Qualitative Research, meta-analysis, small topics. Foundations of Quantitative and qualitative Research Design. Identify different types of study design, including observational, pre-experimental and experimental designs, and their inherent threats to internal and external validity, **(5 hrs)**
4. Variables – types, example. Describe the basic issues related to measurement of variables. (2hours)
5. Confounders and Bias: Confounding, control of confounding. Bias- types, control; blinding- types, double dummy technique; randomisation – methods,measurement levels (3 hrs)
6. Data Analysis and Interpretation: (20 hours)
   6.1. Gaussian curve, hypothesis testing **(1hr)**
   6.2. Confidence interval, p-value, effect size, power **(1hr)**
   6.3. Types of error, reducing error in test **(1 hr)**
   6.4. Parametric and non-parametric tests for difference between groups: data required, example (2 hrs)
   6.5. Chi-square test, Mc Nemar test- Assumption, example, interpretation **(2 hrs)**
   6.6. Tests for ordinal data- Assumption, example, interpretation **(2 hrs)**
   6.7. Central limit theorem, t-distribution, different t-tests- Assumption, example, interpretation (2 hrs)
   6.8. One way Anova- Assumption, example, interpretation, source of variation, post hoc tests (2 hrs)
   6.9. 2 and n- way Anova, multivariate Anova- Assumption, example, interpretation **(2 hrs)**
   6.10. Relative risk, odds ratio, survival studies **(1 hr)**
   6.11. Correlation- Types, Assumption, example, interpretation **(2 hrs)**
   6.12. Regression- Types, Assumption, example, interpretation **(2 hrs)**

   6.13. Topic selection, defining objective and research question, research hypothesis (1 hour)
   6.14. Research report writing, types of report, draft report and presentation and dissemination plan **(2 hours)**
7. Data entry in SPSS and other softwares – Lab Practice **(2hrs).**
   Non-parametric tests (SPSS)- 2hrs,
   T- tests, One- way Anova (SPSS)- **2 hrs**
   Correlation, Regression (SPSS)- **2hrs**

PHAR 414 Lab Literature Survey and Project Design Practical

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

Books and Other Resources Recommended

1. Health Research Methodology- A guide for Training in Research methods. WHO.
2. Green, J. 2004. Qualitative methods for health research. 2nd ed. London: Sage.
3. Methodology and Techniques of Social Research by Bhandarkar and Wilkinson. Himalyan Publishing House
4. Research methodology- Methods and Techniques By CR Kothari- Wiley Eastren limited.
5. Polagar, S. 1995. Introduction to research in the health sciences. 3rd ed. Edinburgh: Churchill Livingstone.
6. A guide for Research proposal writing, National science Foundation.
7. Mike Saks and Judith Allsop. Researching Health Qualitative, Quantitative and Mixed Methods. Sage. ISBN: 978-1-4129-0364-6. Required.
8. Dr Katherine Jones and Katherine Hooper. Researching Health Companion. Sage.
9. S. Polgar and S.A. Thomas Introduction to Research in the Health Sciences, 5th edition. Churchill Livingstone Elsevier, New York (2008).
10. Denise F Polit and Cheryl Tatano beck- Nursing Research- Principles and Methods.7th edition.
11. Albert P.S., and Borkowf, C.B., 2002. "An introduction to biostatistics: randomization, hypothesis testing and sample size," in John I. Gallin (ed.), *Principles and practice of clinical research*, San Diego: Academic Press,
12. Brody, B.A., 1998. *The Ethics of Biomedical Research: An International Perspective*, Oxford: Oxford University Press.
13. Council for International Organizations of Medical Sciences, 2002. *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS.
14. Brett A, Grodin M (1991). Ethical aspects of human experimentation in health services research. JAMA 265:1854-57.
15. BEVERLEY HANCOCK - Trent Focus for Research and Development in Primary Health Care: An Introduction to Qualitative Research. Division of General Practice , University of Nottingham.
16. NATASHA MACK • CYNTHIAWOODSONG, KATHLEEN M.MACQUEEN • GREG GUEST • EMILY NAMEY - Qualitative Research Methods: A DATA COLLECTOR'S FIELD GUIDE. Family Health International.

PHAR 415 Forensic Pharmacy [45 hrs]

Unit – 1: Introduction (2 hours)
History of pharmaceutical legislation, Pharmaceutical industry and pharmaceutical education in Nepal and Global Perspective.

Unit – 2: An elaborate study of the following: (30 hours)

- 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

Unit – 3: A brief account on the following: (13 hours)

- Regulatory provisions for veterinary, ayurvedic and other system of medicines
- Company Act of Nepal
- Patents Act 1970.
- National Health Research Council Act
- Professional councils
- Narcotic drugs control act relating to pharmaceutical product and the relation of act with Drugs Act, 1978
- Drugs banned in Nepal and the reason of drug banning
- Introduction Regulatory affairs in INDIA(Pharmacy act 1948, Drugs and cosmetics act 1940, Narcotic drugs and pdychotropic substances act 1985)
- A brief account about the Drug & Cosmetic Act of UK, Australia and USA.

Books and Other Resourses Recommended

1. Drug Act of Nepal and Regulations under it.
2. Forensic Pharmacy by B.M. Mithal
3. Laws of drugs in India – Hussain
4. Intellectual Property Law by R.K. Nagarajan
5. Text book of forensic pharmacy by C.K.Kokate and S.B.Gokhale published by Pharma book syndicate.

PHAR 416 Dispensing and Community Pharmacy [45 hours]

Unit-1: Community Pharmacy (4 hours)

1.1. Definition, Scope of community pharmacy, different types of community pharmacy.

1.2.Professionalism in the Community Pharmacy Setting.

1.3. Roles and responsibilities of Community pharmacist, Code of Ethics.

Unit-2: Entrepreneurship in Community Pharmacy and developing business plan. **(2 hrs)**

Unit-3: Pharmaceutical care: Definition and Principles of Pharmaceutical care. **(2 hrs)**

Unit-4: Community Pharmacy Management **(12 hrs)**

4.1. Selection of site, Space layout, and design, Pharmacy workflow

4.2. Staff, Materials- coding, stocking

4.3. Legal requirements and legal structure of ownership.

4.4. Maintenance of various registers

4.5. Computerization of Pharmacy

4.6. Documentation in Community pharmacy

4.7. Patient care process in Community pharmacy

Unit-5: Inventory Control: Purchasing and Inventory control in community pharmacy. **(3hrs)**

ABC, VED, EOQ, Lead time, safety stock

Unit-6: Prescription: Handling of prescription, source of errors in prescription, care required in dispensing procedures including labeling of dispensed products. (**2 hrs)**

Unit-7: Pharmaceutical calculations **(3 hrs)**

Posology, calculation of doses for infants, adults and elderly patients; Enlarging and reducing recipes percentage solutions, allegation, alcohol dilution, proof spirit, isotonic solutions, displacement value etc.

Unit-8: Communication skills in Patient counselling (**6 hrs)**

Need for good communication, Key communication skills, strategies to overcome barriers. Patient compliance: Definition, Factors affecting compliance, role of pharmacist in improving the compliance. Patient information leaflets- content, design, & layouts, advisory labels.

Unit-9: Health screening services: (8 hrs)

Definition, importance, methods for screening, responding to symptoms. Role of Pharmacist in OTC drugs, Immunization, Nutrition and Dietary supplements. Smoking cessation, Obesity, Hypertension, Diabetes mellitus (TYPE II) and Family planning.

Unit-10: Good Community Pharmacy Practice: (3 hrs)

Requirements of premises/layout, equipments, manpower, of material, storage and inventory control services, documentation.

PHAR 416 Lab Community Pharmacy Practical

1. Categorization and storage of Pharmaceutical products bases on legal requirements of labeling and storage.
2. Prescription handling and identification of drug interactions, incompatibilities.
3. Health screening services and study of equipments for:- Blood glucose determination (Glucometer), Blood pressure (BP apparatus) and Lung function test (Peak flow meter)
4. Layout and Design of community pharmacy to incorporate all pharmaceutical care services.
5. Study of OTC medications List & Available brands.
6. Interpretation of various pathological reports of blood and urine.
7. Techniques of administration of special dosage forms of drugs : Discussion and overhead picture presentation on proper techniques of administration of :-Inhaler, Eye drops and ointment, Ear drops, Nose drops, Dry syrups, Suppositories and Vaginal pessaries

   (Demonstration of these actual dosage forms and hands on experience at using them)
8. Problem solving / patient care analysis in pharmacy practice, taking drug history, patient counselling role play.
9. Project report on visit to the nearby Community for Counseling on the rational use of drugs and aspects of health care.

Books and Other Resources Suggested

1. Churchill Livingstone, Edalker and Edwards- Clinical Pharmacy and Therapeutics 2nd ed. 1999
2. Clive Edwards and Paul Stillman - Minor Illness or Major Disease? Responding to symptoms in the Pharmacy, Pharma Press 1995.
3. Robinson Harma - Patient Care in Community Practice, A Handbook of Non Medical Healthcare, Pharma Press 1989.

4. Melanie J. Rantucci- Pharmacists talking with Patinents, A guide to Patient Conseling. Williams and Wilkins. 1997.
5. Cynthia Knapp Dlugosz, The Practitioner's quick reference to Non Prescription Durgs. American Pharmacists Association. 2009.
6. Jean Venable, Lynne Roman, Kristin Weitzel, Community Pharmacy Practice. American Pharmacists Association. 2009.
7. WHO Publications: Role of Pharmacist in Health Care, Good Pharmacy Practice, Operational principle for good procurement practice and WHO Revised drug strategies

EIGHTH SEMESTER

PHAR 421 Hospital Pharmacy (45 hours)

1) History and Development of Hospital, Hospital pharmacy and Clinical Pharmacy in Nepal. 1 hr
2) Organization and Structure 1 hr

   - Hospitals: Definition, Objectives and Functions, Classifications based on various criteria, Organization, Management and health delivery system in Nepal.

3) Hospital Pharmacy: 4 hr
   a) Hospital Pharmacy, Definition, functions and objectives of hospital pharmacy, organization, planning and administration of modern hospital pharmacy services, Location, Layout & flow chart of material and men, personnel, and facilities required, including equipments,
   b) Minimum Standards of practice in Hospital pharmacy.
   c) Qualifications, requirements, abilities and evaluation of hospital pharmacist, responsibilities required for Hospital Pharmacists, workload and remuneration of hospital pharmacist, pharmacist assistants and supporting staffs, Job descriptions.
4) Drug Store Management and Inventory Control 4 hr
   a) Organization of drug store, Types of material stocked, Storage Condition, Budgeting for Drugs.
   b) Purchase and Inventory Control Principles, Purchase procedures, Estimation of drug requirements, Determining drug types and quantities required, Lead time, Monthly consumption, Purchase Specifications, Requisition, Purchase order, Purchase record, Procurement and Stocking. Control on Purchase, Vendor selection, ABC analysis, VED analysis.
5) Drug Distribution Systems In Hospitals 5 hr
   a) Outpatient Dispensing; Method adopted, Guidelines for Hospital Drug Distribution Systems.
   b) Inpatients Dispensing; Type of drug distribution systems; Individual prescription order, Floor stock system, Unit dose dispensing system (centralized and decentralized system), Satellite pharmacy services, Bed side pharmacy, charging policy, labeling.

c) Dispensing of controlled drugs, record keeping and stock maintenance.

d) New dispensing systems: Mechanical Drug Dispensing, Computerized Drug Dispensing.

6) Central Sterile Supply Unit and its management: Type of materials for sterilization, packaging of materials prior to sterilization, sterilization equipments, supply of sterile materials. 2 hr

7) Hospital manufacturing and pre-packaging in the Hospital: 6 hr

a) Economic Considerations, Factors affecting make or buy decision, sterile manufacture and non sterile manufacture, facilities and requirements.

b) Nutritional problems in hospitalized patients, Nutritional assessment and metabolic requirements, Disease specific support, Home parenteral nutrition with calculations

8) Hospital committees: 6 hrs

Role of Pharmacists in different hospital committee and rational use of drugs

a) Drug and Therapeutic committee: Goals and Objectives, functions, role of DTC in drug management Cycle, Structure and organization of DTC

b) Infection control committee

c) Antibiotic monitoring committee

d) Research and Ethics committee

9) Nomenclature and uses of surgical Instruments, Surgical supplies and Surgical Dressings. 2 hrs

10) Managing Formulary process

The Formulary process, The formulary list, Formulary manual, Standard Treatment Guidelines, Assessing New medicines 4 hrs

11) Radiopharmaceuticals 8 hr

Type of radio Pharmaceuticals, Radioactive half life, Units of Radioactivity and Dose, Facilities required for the production of radiopharmaceuticals, Production of 99m Technetium, Measurement of radioactivity (Geiger- Miiller counting, Liquid scintillation counting, Measurement of gamma radiation), Dosing, Radiation Hazards and role of pharmacist

12). Computer application in hospital pharmacy 2 hrs

PHAR 421 Lab Hospital Pharmacy Practical

1. Organizational chart of Hospital and hospital Pharmacy.
2. Layout design and workflow of hospital pharmacy.
3. Demonstration of surgical equipments and surgical dressings.
4. Drug List, Emergency Drug list.
5. Adverse Drug Reaction with causality assessment.
6. Drug dose calculation in Children, pregnancy and geriatric patients.
7. Case studies involving different diseases.
8. Prepare formulary of selective drugs.
9. Visit to Hospital pharmacy and prepare a report. (optional)

Books and Other Resources recommended

1. Lea and Gebiger, William E. Hassan- Hospital Pharmacy 3rd ed. 1974.
2. Birla Publications, Pratibha Nand and RK Khar- A textbook of Hospital and Clinical Pharmacy 1st ed. 2001.
3. Vallabh Publications, PC Dandiya and Mukul Mahur- A textbook of Hospital and Clinical Pharmacy 4th ed. 2005.
4. Churchill Livingstone, Edalker and Edwards- Clinical Pharmacy and Therapeutics 2nd ed. 1999
5. American Pharmaceutical Association, John Rovers and Jay Currie- A Practical Guide to Pharmaceutical Care 3rd ed. 2007.
6. Green and Harris - Pathology and Therapeutics for Pharmacists , Chapman and Hall ISBN 0-412-36000-4
7. Winfield and Richanrds - Pharmaceutical Practice , Churchill Livingstone 1998.
8. Diane M.Collett and Michael E.Aulton, Churchill Livingstone 1990.
9. Clive Edwards and Paul Stillman - Minor Illness or Major Disease ? Responding to symptoms in the Pharmacy, Pharma Press 1995.
10. Alison Blenkinshopp and Paul Paxton - Symptom in Pharmacy, Blackwell Science 1995.
11. WHO Publications: Role of Pharmacist in Health Care, Good Pharmacy Practice, Operational principle for good procurement practice and WHO Revised drug strategies.

PHAR 422 Drug Delivery System (30 hours)

Unit – 1: Polymer Science (2 hours)
Introduction, synthesis of polymers, polymer classification, biodegradation of polymers, properties of polymers, pharmaceutical application of polymers.

Unit – 2: Sustained release formulations (4 hours)
Introduction, concept, advantages and disadvantages. Physicochemical and biological properties of drugs relevant to sustained release formulations, evaluation of sustained release drug formulations.

Unit – 3: Concept and system design for rate-controlled drug delivery (4 hours)
Classification of controlled drug delivery systems, rate-programmed release, activation modulated and feedback-regulated drug delivery systems, effect of system parameters on controlled release drug delivery.

Unit – 4: Mucoadhesive drug delivery systems (6 hours)
Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, mucosal membrane models, mucoadhesive polymers, permeability enhancers, *in vitro* and *in vivo* methods for buccal absorption. Nasal and pulmonary drug delivery systems and its applications.

Unit –5: Parenteral controlled release drug delivery systems (4 hours)
Approaches for injectable controlled release formulations and development of implantable drug delivery systems.

Unit – 6: Targeted drug delivery systems (6 hours)
Principles of targeting, classification, advantages and disadvantages, biological processes and event involved in drug targeting, microspheres, magnetic microspheres, nanoparticles, liposomes, niosomes, dendrimers, resealed erythrocytes, and monoclonal antibodies.

Unit – 7: Protein and peptide drug delivery (4 hours)
Introduction, classification and structure of protein, drug delivery systems for proteins and peptides, manifestation of protein instability and stability.

PHAR 422 Lab Drug Delivery System practical

1. Characterization of polymers.
2. Preparation and evaluation of polymeric microspheres.
3. Preparation and evaluation of microcapsules by different microencapsulation techniques.
4. Preparation and evaluation of matrix tablets using various polymers.
5. Formulation and evaluation of floating tablets.
6. Study on in vitro diffusion of drugs through various polymeric membranes.
7. Preparation and evaluation of buccal mucoadhesives systems.
8. Preparation and evaluation of drug-free polymeric films.
9. Preparation and evaluation of transdermal patches.
10. Preparation and evaluation of floating microspheres.
11. Preparation and characterization of liposomes.
12. Preparation and characterization of niosomes.

13. Study of in vitro dissolution of various sustained release formulations of marketed products.
14. Demonstration of skin sensitivity testing of TDDS on a suitable animal model.

DRUG DELIVERY SYSTEMS
1. Preparation and Evaluation of Matrix Tablets
2. Formulation and Evaluation of Film Coated Tablets.
3. Formulation and Evaluation of Enteric Coated Tablets.
4. Preparation and Evaluation of Transdermal Drug Delivery Systems.
5. Formulation and Evaluation of Mucoadhesive Delivery Systems.
6. Evaluation of Market SR Formulations.
7. Preparation and Evaluation of Alginate Beads.
8. Analytical Method Validation.

Books and Other Resources recommended

1. Fried J.R. Polymer Science & Technology, 2nd edition. Prientice-Hall India Pvt. Ltd.
2. Coleman M.M., Painter P.C. Fundamentals of Polymer Science: An Introductory Text. CRC Press.
3. Lliun Lisbeth, Davis Stanley S. Polymers in Controlled Drug Delivery. Wright Bristol.
4. Robinson J.R., Lee V.H.L. Controlled Drug Delivery. Marcel Dekker, Inc.
5. Juliano R.L., Drug Delivery Systems: Characteristics and Biomedical Applications. Oxford University Press.
6. Chien Y.W. Novel Drug Delivery Systems. Marcel Dekker, Inc.
7. Vyas S.P., Khar R.K. Controlled Drug Delivery-Concepts and Advances. Vallabh Prakashan.
8. Mathiowitz E. Encyclopedia of Controlled Delivery. John Wiley & Sons, Inc.
9. Jain N.K. Controlled and Novel Drug Delivery. CBS Publishers & Distributors.
10. Carstensent J. T. Drugs and Pharm.Sci. Series, vol. 43, Marcel Dekker Inc.
11. Johnson P., Lloyd-Jones, J.G. Drug Delivery Systems: Fundamentals and Techniques. VCH.
12. Audus K.L., Juliano R.L. Targeted Drug Delivery. Springer-Verlag.
13. Lee V.H.L. Peptide and Protein Drug Delivery. Marcelk Dekker, Inc.
14. Guy R.H., Hadgraft G. Transdermal Drug Delivery. Marcel Dekker, Inc.
15. Edith Mathiowitz, Donald E. Chickering, Claus-Michael Lehr. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches and Development. Marcel Dekker, Inc.
16. Kasliwal N. Liposomes/Niosomes As a Drug Delivery System. Lambert Academic Publishing.
17. Dietrich G., Goebel W. Vaccine Delivery Strategies. Horizon Scientific Press.
18. Kaufmann S.H.E. Novel Vaccination Strategies. Wiley-VCH.

PHAR 423 Quality Assurance & Instrumental Analysis (60 hours)

Unit – 1: Quality assurance (10 hrs)

1.1. GMP concept and its components, comparison of requirements of WHO guidelines, US FDA guidelines,

1.2 GLP concept and its components,

1.3. Concept of ISO, difference of GMP guidelines with ISO

1.4. Concept of TQM, Quality Review and Quality Documentation.

1.5. Validation, validation of equipment, validation of analytical procedures.

Unit-2: Instrumental Analysis (50 hours)

2.1. Ultraviolet and visible spectrophotometry: Introduction, absorption laws, instrumentation, types of electronic transition, chromophore concept, auxochrome, absorption & intensity shifts, types of absorption bands, choice of solvent & solvent effects, Woodward-Feiser & Feiser-Kuhn rules for calculating absorption maxima, applications of UV spectroscopy.(12 hrs)

2.2. Fluorimetry: Introduction, principle, factors affecting fluorescence intensity, instrumentation & applications of fluorimetry.(3hrs)

2.3. Infrared spectrophotometry: Introduction, theory of IR spectroscopy, modes of vibration, factors affecting vibrational frequencies, instrumentation, position & intensity of absorption bands, sampling methods, applications of IR spectroscopy, interpretation of IR spectra, limitations of IR spectroscopy.(10 hrs)

2.4. Nuclear Magnetic Resonance spectroscopy including ^{13}C NMR: Introduction, principle, instrumentation, number of signals, chemical shift & factors affecting chemical shift, internal standards, shielding & deshielding effects, solvents in nmr, splitting of signals, spin-spin coupling, coupling constant, double resonance (spin decoupling), nuclear overhauser effect (NOE), introduction to ^{13}C NMR, applications of NMR spectroscopy, interpretation of NMR spectra.(12 hrs)

2.5. Mass Spectrometry: Introduction, principle, instrumentation, mass spectrogram, types of ion produced in mass spectrometer, index of hydrogen deficiency, nitrogen rule, ring rule, interpretation of molecular spectra & applications of mass spectroscopy. (7 hrs)

2.6. Flame Photometry: Introduction, principle, instrumentation, effect of solvent, applications in qualitative & quantitative analysis, methods of quantitative analysis, interferences in flame photometry & limitations of flame photometry.(3 hrs)

2.7. Emission Spectroscopy: Introduction, theory, instrumentation, advantage & disadvantage of emission spectroscopy, applications. (2hrs)

2.8. Atomic Absorption Spectroscopy: Introduction, theory, instrumentation, detection limit & sensitivity, interference, applications of AAS. (2hrs)

2.9. X-ray Diffraction: Introduction, theory, instrumentation, applications.(2hrs)

2.10. Thermal methods: Introduction to thermal methods; principle, instrumentation & application of differential thermal analysis (DTA), differential scanning calorimetry (DSC) & thermogravimetry (TG). (5hrs)

2.11. Radioimmunoassay (3 hrs)

Phar 423 Lab Quality Assurance and Instrumental Analysis Practical

1. Quantitative estimation of formulations containing single drug or more than one drug, using uv-visible spectroscopy.

2. Estimation of Na, K, Ca ions using flame photometry.
3. Estimation of riboflavin, quinine using flame fluorimetry.
4. Workshop to interpret the structure of simple organic compounds using UV, IR, NMR and MS.

Books and Other Resources recommended

1. Skoog, et al : Fundamentals of analytical chemistry, Thomson Brooks/Cole
2. William Kemp: Organic Spectroscopy (3rd Ed.) 1991, Macmillan Press Ltd., London.
3. R. M. Silverstein, G. C. Balller and T. C. Morrill: Spectrometric Identification of Organic Compounds. (5thEd.) 1991, John Wiley and Sons, Inc. London.
4. John R. Dyer: Applications of Absorption Spectroscopy of Organic Compounds, 1965, Prentice-Hall, Inc., London.
5. BK Sharma: Instrumental & Chemical Methods of analysis: Goel Publication
6. Chatwal & Anand: Instrumental & Chemical Methods of analysis: Himalayan Publication
7. Beckett A H and Stenlake J B, Practical Pharmaceutical Chemistry Vol. II, The Athlone Press of the University of London.
8. G. Gauglitz and T. Vo-Dinh; Handbook of Spectroscopy; Wiley-VCH

PHAR 424 Clinical Pharmacy (30 hours)

1) Introduction to Clinical Pharmacy, Objectives of clinical pharmacy, Scope of Clinical pharmacy, Role of Clinical pharmacists (1 hr)
2) Patient data analysis and Prescribing guidelines: (5 hrs)
   Interpretation of Clinical laboratory tests used in the evaluation of common disease states, Haematological parameters, Urine examination, Stool Examination, liver function tests, pulmonary function tests. Patient's Data collection. Paediatric patients, Geriatric patients, Pregnant and breast feeding women.
3) Adverse drug reactions: ADRs with special emphasis on epidemiology, classification, risk factors, monitoring and detecting ADR, assessing causality, reporting ADRs. (4 hrs)
4) Drug interactions: Define drug-drug and drug-food interactions. Classify and explain mechanism of drug-drug interactions. (5 hrs)
5) Drug dependence and Drug abuse (1 hr)
6) Describe the investigational drugs and phases of clinical trials, pharmacist's role in clinical trials, statistical methods of interpretation, legal and ethical considerations. (4 hrs)
7) Therapeutic drug monitoring and role of pharmacist. (4 hrs)
8) Drug and poison information services: (6 hrs)

Introduction of drug information, Resources available, Design of literature searches, Critical evaluation of drug information and literature, Preparation of written and verbal reports and Development of a drug information data base and emergency treatment of poisoning.

Books and Other Resources recommended

1. Birla Publications, Pratibha Nand and RK Khar- A textbook of Hospital and Clinical Pharmacy 1st ed. 2001.
2. Vallabh Publications, PC Dandiya and Mukul Mahur- A textbook of Hospital and Clinical Pharmacy 4th ed. 2005.
3. Churchill Livingstone, Edalker and Edwards- Clinical Pharmacy and Therapeutics 2nd ed. 1999
4. American Pharmaceutical Association, John Rovers and Jay Currie- A Practical Guide to Pharmaceutical Care 3rd ed. 2007.

5. Green and Harris - Pathology and Therapeutics for Pharmacists , Chapman and Hall ISBN 0-412-36000-4
6. Winfield and Richanrds - Pharmaceutical Practice , Churchill Livingstone 1998.
7. Clive Edwards and Paul Stillman - Minor Illness or Major Disease ? Responding to symptoms in the Pharmacy, Pharma Press 1995.
8. Current Medical Diagnosis & Treatment Lawrence M. Tierney,Jr.Stephen J. McPhee,Maxine A. Papadakis

PHAR 425 Project Work