



# 1. Pharmaceutical analysis & instrumentation

Different techniques of pharmaceutical analysis, Preliminaries and definitions:

Significant figures, Rules for retaining significant digits, Types of errors, Mean deviation, Standard deviation, Statistical treatment of small data sets, Selection of sample, Precision and accuracy.

Fundamentals of volumetric analysis: Methods of expressing concentration, primary and secondary standards, Acid Base Titrations, Oxidation Reduction Titrations, Precipitation Titrations, Gravimetric Analysis, Non-aqueous titrations, Complexometric titrations, Diazotization titrations, Kjeldahl method of nitrogen estimation, Karl-Fischer aquametry, Chromatography (TLC, HPLC, GC, GC/MS, LC/MS).

The Theoretical Aspects, Basic Instrumentation, Elements of Interpretation of Spectra, and Applications (quantitative and qualitative) of the Following Analytical Techniques:

(Ultraviolet and visible spectrophotometry, Fluorimetry, Infrared spectrophotometry, Nuclear

Magnetic Resonance spectroscopy (proton technique only), Mass Spectrometry, Flame Photometry, Atomic Absorption Spectroscopy).

GLP, ISO 9000, ISO 17025, TQM, Quality Review and Quality documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data, Validation, quality audit: validation of equipment, validation of analytical procedures.



# Community Pharmacy, Social Pharmacy and Public Health

## Community Pharmacy

- Narcotics management and record keeping.
- Prescription and prescription handling
- Entrepreneurship and business plan.
- Good Pharmacy practice
- Patient Care process in community pharmacy
- Patient communication and counseling.
- New role of community pharmacists.
  
- Healthcare management models
- Healthcare delivery system in Nepal.
  
- Elements, Principles, Implementation of PHC (in terms of WHO and government of Nepal).
- Role of pharmacists in primary healthcare.

## Research in Pharmacy Practice

- Descriptive Studies (Case report, Case series and Ecological studies), Analytical Studies (Case control studies, Cohort studies), Experimental Studies (True experimental studies, Quasi experimental studies). Methods of quantifying drug interactions/ADR and adherence to drug therapy in pharmacoepidemiology.)Sources of Pharmacoepidemiology data.
  
- Resources for Drug Development
  
- Input and outcome in pharmacoeconomics
  
- ECHO model
  
- Cost (Direct, Indirect and Intangible)
  
- Equity, Efficacy and effectiveness
  
- Cost of Illness (COI), Cost Benefit Analysis (CBA), Cost Effectiveness Analysis (CEA), Cost Minimization Analysis (CMA), Cost Utility Analysis (CUA).
  
- Discounting and sensitivity analysis
  
- Health Technology Assessments



## Forensic Pharmacy (Pharmacy Law and Ethics)

Test the knowledge underpinning the legal and professional practice of Pharmacy.

### 1.1. Acts and Regulations Governing Pharmacy Practice in Nepal

- Drug Act 2035
- Drug Consultative Council and Drug Advisory Committee Regulation 2038
- Drug Registration Regulation 2037
- Drug Inquiry and Inspection Regulation 2040
- Drug Standard Regulation 2043
- Drug Manufacturing Code 2041
- Nepal Pharmacy Council act 2057
- WHO GMP
- Others act relating to pharmacy practice (Consumer act, Narcotic act).

### 1.2. Laws relating to Industrial Practice: Procedure for establishment of industry.

- Procedure for Product license.
- Procedure for sale and distribution of medicines.
- Procedure for import export of medicines.
- Procedure for marketing license.
- Procedure for advertisement.
- Procedure for establishment of pharmacy.
- Procedure for Clinical trial.
- the legal requirements for the sale and supply of medicines and controlled drugs from pharmacies
- The implications and liability attached to the supply of licensed, "off-label" or unlicensed medicines.
- Label and labeling requirements.
- Procedure for being a registered pharmacist.



# Clinical and Hospital Pharmacy

## Hospital Pharmacy: Organization and Structure of hospital pharmacy

**Drug and Therapeutic Committee:** Goals and objectives of the DTC and Functions of DTC

- Structure and organization of DTC

### Managing Formulary Process

Formulary List/Essential Medicine List/Formulary Manual/Standard Treatment Schedule/Criteria in Medicine Selection

### Drug Information Services

Assessing New Medicines/ Primary/Secondary/Tertiary

### Drug Store Management and Inventory Control

Drug Management Cycle/ ABC analysis, Therapeutic Category analysis, VED analysis/Daily Defined Dose (DDD)/WHO/INRUD Drug use indicators

**Drug distribution Systems in Hospitals:** Inpatient and outpatient

Application of computers in Pharmacy.

Central Sterile Supply Unit and their Management

Manufacture of Sterile and Non-sterile Products/ Handling of radioisotopes and radiopharmaceuticals.

## Clinical Pharmacy: Differentiating minor illness from more serious disease

- Symptoms of conditions that require referral to a medical or other healthcare practitioner
- Conditions not requiring referral and how they may appropriately be treated by non-prescription medicines, by short-term action that does not involve medication or by lifestyle change.

### Non-prescription remedies

- Actions and licensed uses of medicinal products available without prescription that are commonly used to treat minor ailments.

### Pharmacovigilance, Adverse Effects and Drug Interactions

Type of ADR and Drug Interactions/Causality and severity assessments/ Drug-drug interactions, Drug-food interactions the correct actions to take in response to a client reporting an adverse drug reaction, including the national reporting scheme in Nepal.

### Interpretation of common test results

- the normal ranges for blood pressure and key blood components
- the normal ranges for key parameters of bodily function
- the normal ranges for therapeutic blood levels of commonly used drugs with a narrow therapeutic index
- the implications of figures outside these ranges
- Selection of appropriate diagnostic or physiological testing techniques to inform clinical decision making

### Patient data collection, data analysis and prescribing guidelines.

#### Prescribing in Special Populations

Paediatric, Geriatric, Pregnant, breast feeding, Renal and Hepatic failure patients.

Requirements for the establishment of retail and whole sale drug store.



## Pharmacognosy. Medicinal Chemistry and Natural Product Chemistry

1. History of Medicinal Chemistry and Drug discovery. Physicochemical properties of drug molecules.
2. Biotransformation.
3. Prodrugs.
4. Phases of Clinical trials.
5. Introduction to QSAR and CADD.
6. Physicochemical properties, mechanism of action, structure activity relationship (SAR) of the following groups of Drugs:
  - 6.1. Cholinergic and Anticholinergic Drugs (Acetylcholine prototype, Carbachol, Neostigmine and similar drugs, Organophosphate and Atropine prototype drugs).
  - 6.2. Adrenergic and Antiadrenergics (Catechol amines and other sympathomimetics), Alpha and Beta blockers.
  - 6.3. Antihistaminic and Antiulcer (H1 and H2 blockers with the examples of common drugs used in therapy).
  - 6.4. NSAIDS (Salicylates, Paracetamol, Ibuprofen, Diclofenac, Nimesulide, mefenamic acid).
  - 6.5. Oxytocin, and Prostaglandins
- 6.6. Steroids and other hormonal analogues: Glucocorticoides, Mineralocorticoides, Estrogens (Estradiol, Diethylstilbestrol), Progesterone, including Oral Contraceptives, Testosterone, Thyroid and antithyroid drugs, Insulin and Oral Hypoglycemics.
- 6.7. Cardiovascular Agents: Cardiac glycosides (Digoxin), Glyceryl nitrate, Propranolol. Antihypertensive agents: Reserpine, Prazosin, Terazosin, Clonidine, Hydralazine, Sodium Nitroprusside, Minoxidil, Captopril, Enalapril, Losartan, Nifedipine.  
Diuretics: Acetazolamide, Hydrochlorothiazide, Furosemide, Spironolactone and Mannitol.  
Anticoagulants: Heparin and Warfarin. Antiplatelet drugs: Aspirin, Dipyridamol, Streptokinase.
- 6.8. Local anti-infective agents (Ethyl Alcohol, isopropyl alcohol, formaldehyde, phenols, cresol, hydrogen peroxide, povidone iodine, halozone, Chlorhexidine gluconate, Gentian violet, Nitrofurazone, Merbromin. Salicylic acid and benzoic acid).
- 6.9.: Sulphonamides Sulphamethoxazole and trimethoprim, Sulphadimethoxin, Sulfacetamide and silver sulphadiazine).
- 6.10. Beta-lactam Antibiotics and Beta-lactam inhibitors
- 6.11. Tetracycline and Chloramphenicol. 6.12. Aminoglycosides and macrolides
- 6.13. Quinolones, Antituberculars and Antileprotics
- 6.14. Antimalarials, Antiprotozoals, Antifungals, Antivirals, Anthelmintics and Antineoplastics.
- 6.15. Vitamins and enzymes
- 6.16. Importance of inorganic compounds in pharmacy and medicine (Acidifying agents, Antacids, Protective and Adsorbents, Cathartics ;), Intra- and Extra-cellular Electrolytes, Essential and Trace Elements, Topical Agents(Protective, Astringents and Anti-infectives).



## Pharmacognosy and Natural Product Chemistry

1. Plant, Animal, Microorganism and tissue culture as a source of drugs and pharmaceutical aids. Traditional healer's practices in Nepal.
2. Classification of Crude drugs.
3. Role of Medicinal & aromatic plants in National Economy. Medicinal Plants occurring in various climatic zones of Nepal. Method of medicinal plant collection, preparation of herbarium and their storage. Complementary and Alternative system of medicine practices in Nepal. (Ayurvedic, homeopathic, traditional Chinese, siddha system, unani system and Amchi system).
4. Adulteration of crude drugs and their detection by organoleptic, microscopic, physical, chemical and biological methods of evaluation. WHO guide lines of the standardization of Herbal raw materials and finished products.
5. Plant metabolites: primary & secondary metabolites & fundamental metabolic pathways—the acetate, shikimate, mevalonate, and deoxyxylulose phosphate pathways.
6. ferent Plants are containing Resins, Volatile oil, Glycoside and Alkaloid containing drugs.
7. General methods associated with the phytochemical investigation of herbal drugs- Authentication of plant materials, various methods of extraction, general ideas of isolation, purification of the chemical constituents and characterization of isolated compounds. Drug Development from novel natural molecule.
8. Utilization and production of phytoconstituents such as Taxene, Resin, Alkaloids, Sennosides, Digitalis glycosides, Volatile oil and Polyphenolic compounds. Chemistry of Alkaloids and Glycosides. Herb collection centers around Nepal.



## 2. Pharmacology and Therapeutics

1.1..Pathophysiology of Common Diseases: Asthma, diabetes, rheumatoid arthritis, gout, ulcerative colitis, neoplasia, psychosis, depression, mania, epilepsy, acute and chronic renal failure, hypertension, angina, congestive heart failure, myocardial infarction, congestive heart failure, peptic ulcer, anemia, hepatic disorders, tuberculosis, urinary tract infections, Helmenthasis, Failariasis, Malaria, Polio, Kalazar and sexually transmitted diseases.

1.2.Fundamentals of general pharmacology: Drugs acting on Peripheral Nervous System: Neurohumoral transmission, Parasympathomimetics,Parasympatholytics, Sympathomimetics, Adrenergic receptor and neuron blocking agents,Ganglion stimulants and blocking agents, Neuromuscular blocking Agents, Local anesthetic Agents.

Drugs acting on Central Nervous System: Neurohumoral transmission in the C.N.S., General Anesthetics, Alcohols and disulfiram, Sedatives,Hypnotics, Anti-anxiety agents and Centrally acting muscle relaxants, Psychopharmacological: agents (anti-psychotics, Antidepressants, Anti-epileptics drugs, Anti-Parkinsonian drugs, Analgesics, Antipyretics, Narcotic analgesics and antagonists, C.N.S. stimulants, Drug Addiction and Drug Abuse.

Drugs acting on Cardiovascular System: Drugs for congestive cardiac failure, Antihypertensive drugs, Anti-anginal and Vasodilator drugs, including calcium channel blockers and beta adrenergic antagonists, Antiarrhythmic drugs, Anti-hyperlipedemic drugs, Drugs used in the therapy of shock.

Drugs Acting on the Hemopoietic System: Hematinics, Anticoagulants, Vitamin K and hemostatic agents, Fibrinolytic and anti-platelet drugs, Blood and plasma volume expanders.

Drugs acting on urinary system: Fluid and electrolyte balance, Diuretics.

Autacoids: Histamine, Antihistaminic drugs, 5-HT- its agonists and antagonists, Prostaglandins, thromboxanes and leukotrienes, Angiotensin, Bradykinin and Substance P and other vasoactive peptides, nonsteroidal anti-inflammatory and anti-gout agents.

Drugs Acting on the Respiratory System: Anti-asthmatic drugs including bronchodilators, Anti-tussives and expectorants, Respiratory stimulants.

Drugs acting on the Gastrointestinal Tract: Antacids, Anti-secretory and Anti-ulcer drugs, Laxatives and anti-diarrhoeal drugs, Appetite Stimulants and Suppressants, Emetics and anti-emetics, Miscellaneous: Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.

Pharmacology of Endocrine System: Hypothalamic and pituitary hormones, Thyroid hormones and anti-thyroid drugs, parathormone, calcitonin and Vitamin D, Insulin, glucagons, incretins, oral hypoglycemic agents and insulin analogs, ACTH and corticosteroids, Androgens and anabolic steroids, Estrogens, progesterone and oral contraceptives, Drugs acting on the uterus.

Chemotherapy: General Principles of Chemotherapy, Bacterial resistance; Sulfonamides and cotrimoxazole,

Antibiotics- Penicillins, Cephalosporins, Aminoglycosides, Chloramphenicol, Macrolides, Tetracyclines, Quinolones, fluoroquinolones and Miscellaneous antibiotics; Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, HIV and AIDS, urinary tract infections and



sexually transmitted diseases, malaria, amoebiasis and other protozoal infections and Anthelmintics. Chemotherapy of malignancy and immunosuppressive agents.

Principles of Toxicology: Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates, opioids, organophosphorous and atropine poisoning, Heavy metals and heavy metal antagonists.

Basic Concepts of Pharmacotherapy:

Clinical Pharmacokinetics and individualization of Drug therapy, Drug delivery systems and their Biopharmaceutics & Therapeutic considerations, Drugs used during infancy and in the elderly persons (Pediatrics & Geriatrics), Drugs used during pregnancy, Drug induced diseases, The basics of drug interactions, General principles of clinical toxicology, Common clinical laboratory tests and their interpretation.

Important Disorders of Organs, Systems and their Management:

Cardio-vascular disorders- Hypertension, Congestive heart failure, Angina, Acute myocardial infarction, Cardiac arrhythmias.

CNS Disorders: Epilepsy, Parkinsonism, Schizophrenia, Depression.

Respiratory disease- Asthma. Gastrointestinal Disorders- Peptic ulcer, Ulcerative colitis, Hepatitis, Cirrhosis.

Endocrine Disorders- Diabetes mellitus and Thyroid disorders.

Infectious Diseases- Tuberculosis, Urinary tract infections, Enteric infections, Upper respiratory infections.

Hematopoietic Disorders- Anemias, Joint and Connective tissue disorders- Rheumatic diseases, Gout and Hyperuricemia.

Neoplastic Diseases- Acute Leukaemias, Hodgkin's disease. Therapeutic Drug Monitoring, Concept of Essential Drugs and Rational Drug use.





## Pharmaceutical technology, biopharmaceutics & dosage form design

Dehumidification and Humidity Control of an industry, designing of dosage forms (Pre-formulation studies).

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: Stabilization and stability testing protocol for various pharmaceutical products. ICH Guidelines for stability testing of formulations. Ionization constant  $-pK_a$ ; pH solubility profile and common ion effect  $-K_{sp}$ ; 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.

Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc., and their influence on formulation and stability of products.

Manufacturing and Quality control of: Liquid Dosages Forms, Semisolid Dosage Forms, Pharmaceutical Aerosols, Solid dosage forms, Ophthalmic Preparations, Cosmetic Preparations, and Parenteral Products.

Packaging of Pharmaceutical Products, Performance evaluation methods of dosage forms (Dissolution, Bioavailability and Bioequivalence), Industrial Hazards and Safety Precautions.

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 Assurance: Concept, function and organizational Approach.

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

Concept of ISO, difference of GMP guidelines with ISO. Concept of TQM, Quality Review and Quality Documentation. Validation, validation of equipment, validation of analytical procedures.

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.

Pharmacokinetics of drug absorption (Zero and First order kinetics), Compartment kinetics (Concepts and their importance in the study of pharmacokinetics. One compartment open model. Assessment of pharmacokinetic parameters from plasma and urine data after i. v. bolus, i.v. infusion, i. v. injection with loading dose and oral administration. Percent absorbed time plot and determination of absorption rates based on one compartment model. Introduction to ‘Two compartment model) Clinical Pharmacokinetics.