

VEER NARMAD SOUTH GUJARAT UNIVERSITY

B. Pharmacy

2003-04

FOURTH YEAR

Paper No.	Subject	Maximum Marks for					
		Theory			Practical		
		Ex	Se	Total	Ex.	Se	Total
401	Pharmacy Practice-II (Community Pharmacy)	60	40	100	70	30	100
402	Pharmacy Practice-III (Clinical Pharmacy and Therapeutics)	60	40	100	70	30	100
403	Bio-pharmaceutics and Pharmacokinetics	60	40	100	70	30	100
404	Industrial Pharmacy-II	60	40	100	70	30	100
405	Medicinal Chemistry-II	60	40	100	-	-	-
406	Pharmaceutical Analysis-II	60	40	100	70	30	100
407	Pharmacognosy-III	60	40	100	70	30	100
408	Pharmaceutical Business Management	60	40	100	-	-	-

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B. PHARM FOURTH YEAR

2006-2007

PH-401 PHARMACY PRACTICE-II (COMMUNITY PHARMACY)

THEORY (50 hours)

1. Introduction to the concept of community pharmacy, its activities and professional responsibilities and professionals in trade versus traders in profession.
2. Organization and structure of retail and wholesale pharmacy, factors to be considered for location of retail pharmacy, legal and infrastructure requirements for establishing retail pharmacy, maintenance of records of retail and wholesale pharmacy.
3. Community pharmacy management, finance, personnel, infrastructure, materials, computers and drug information resources.
4. Polypharmacy and its implications.
5. Role of community pharmacist in health care system as per WHO guidelines.
6. Community pharmacies in primary health care services, family planning, first aid, communicable diseases and non-communicable diseases.
7. Community pharmacist as health educator and role of community pharmacist in population control, first aid and prevention of communicable diseases like sexually transmitted diseases and AIDS.
8. Community pharmacist as a source of drug and poison information.
9. Important techniques adopted in community health care services (BP/Pulse/Temperature, Respiration rate, and parenteral drug administration).
10. Code of ethics for practicing pharmacists: (Community and ward pharmacy practice hospital and clinical)
11. Prescribed medication order- interpretation and legal requirements.
12. Over-the-counter (OTC) drugs (non-prescription) and prescription drugs sales.
13. The concept of Essential drugs and Rational drug use.
14. Patients counseling general considerations, importance, steps and procedure involved.
15. Communication skill- Principle and elements of communication skills, non-verbal communication in pharmacy, barriers in communication, listening skills, questioning skill, explaining skills and ethics in communication.

PRACTICAL (50 Hours)

1. Interpretation of ten prescriptions (five each of Govt. hospital and private hospital) to identify incompatibilities and irrationality.
2. Identification of use of self-monitoring medical instruments like glucometer, BP apparatus, inhalers, sprays and diagnostic indicators.
3. Demonstration of important techniques like recording of BP, pulse, temperature, respiration rate, artificial respiration and parenteral drug administration.
- 4.

5. First aid treatment.
6. Visit to two-community pharmacies for compliance of Drug and cosmetics Act, 1940 and rules, 1945.
7. Prepare questionnaire covering all aspects of selected diseases like T.B., Malaria, Diabetes, cerebro-vascular diseases, Asthma, Diarrhoea, Hepatitis and AIDS. Submit minimum ten duly answered questionnaires (self prepared) from the patients of any of the above diseases.
8. Prepare charts (minimum two) aiming to counsel patients suffering from the disease like- AIDS, Cancer, Diabetes, T.B. Malaria, Typhoid, Dysentery, and Hypertension.
9. Group of students (each group comprises of ten students) should arrange a camp to nearby village and submit a report aiming to-
 - a. Health status of the village (Refer PHE records).
 - b. Health care provided by PHE in the visited village.
 - c. Particular disease commonly found in the visited village.
 - d. Availability of private clinics with or without qualified doctors.
 - e. Interviews of villagers with regard to their knowledge in vaccination, HIV and alcoholism.

If possible, students should arrange lecture(s) to teach villagers for importance of vaccination, prevention of HIV infection, oral contraceptive pills and adverse effects of alcoholism.

A complete report with interviews (recorded cassettes) along with the letter duly signed by Sarpanch of the village should be submitted.

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PH-402 PHARMACY PRACTICE-III (CLINICAL PHARMACY AND THERAPEUTICS) THEORY (75 hours)

- 1. Definition, scope, history and development of clinical pharmacy.**
- 2. Introduction to clinical trials.**
- 3. Role of the clinical pharmacist:** Drug therapy monitoring: medication charts review, clinical review, Therapeutic drug monitoring.
Patient data analysis: Clinical laboratory tests used in the evaluation of common disease states, interpretation of test results of liver function tests, pulmonary function tests, haemogram and renal function tests. The patient's case history, its structure and use in evaluation of drug therapy.
- 4. Basic and general principles of drug delivery:**
Monitoring of drug therapy: Therapeutic, pharmacokinetic and pharmacodynamic monitoring of drug therapy.
Adverse reactions to drugs: Incidence, classification and surveillance methods of adverse reactions to drugs and its management.
Pharmacogenetics: Pharmacokinetic and pharmacodynamic aspects of pharmacogenetics.
Drug interactions: Incidence, pharmacokinetic and pharmacodynamic drug interactions.
Patient compliance: Factors, which affect compliance, methods of measuring and improving drug compliance.
Individualization of drug therapy.
Pharmacology of placebos: Mode of action, uses and abuse, adverse effects and factors, which influence the response of placebos.
General prescribing guidelines in pediatric and geriatric patients, pregnancy and lactation.
- 5. Clinical pharmacokinetics and dosage monitoring:** Introduction to clinical pharmacokinetics, physiologic pharmacokinetic model and its clinical applications. Clearance-renal clearance and non renal clearance, organ extraction and models of hepatic clearance. Estimation and determination of bioavailability, calculation of loading and maintenance dose, dose adjustment in renal failure, hepatic dysfunction, geriatric and paediatric patients.
- 6. Pharmacotherapy of diseases:** Pathophysiology, drug therapy and critical analysis of rational use of drugs in the following disorders:
Cardiovascular disorders: Hypertension, congestive heart failure, ischaemic heart disease, arrhythmias and hyperlipidaemias.
Respiratory disorders: Asthma and chronic obstructive airways disease.
Renal disorders: Acute and chronic renal failure and drug dosing in renal impairment.
Haematological disorders: Anaemia and drug induced haematological disorders.

Endocrine disorders: Diabetes, thyroid disease and hormone replacement therapy.

Nervous disease: Epilepsy, Parkinson's disease and headache.

Psychiatric disorders: Schizophrenia, depression, anxiety disorders and sleep disorders.

Gastrointestinal diseases: Ulcer disease, inflammatory bowel diseases, hepatic alcoholic liver diseases and drug induced liver disease.

Infectious disease: Respiratory tract infections, gastro-enteritis, pneumonia, typhoid, urinary tract infections, tuberculosis, leprosy, protozoal infections, helminthiasis, sexually transmitted disease and AIDS.

PRACTICAL (50 hours)

1. Hospitals posting in departments like General medicine and paediatric to
2. complement the lectures by providing practical & clinical discussion.
3. Students are to make at least any Five case presentation on: On Hypertension,
4. congestive cardiac failure, angina pectoris, asthma, COPD, diabetes mellitus, peptic
5. ulcer, anaemia, tuberculosis, pneumonia, malaria, enteric fever, alcoholic liver disease, amoebiasis and hepatitis.
6. Patient medication history interview.
Patient medication counseling – at least 2 exercises.
Answering drug information questions- at least 3 exercises.
Case studies relating to laboratory investigations of haematology (anaemia), liver function tests, thyroid function test, renal function tests and cardiac enzyme studies.
Analysis of prescriptions for clinically significant drug-drug interaction – at least 3 exercises.

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PH-403 PHARMACY PRACTICE-III BIOPHARMACEUTICS AND PHARMACOKINETICS THEORY (50 hours)

1. **Introduction to Biopharmaceutics and pharmaco-kinetics.** Various terms used and their role in related discipline.
2. **Bio-pharmaceutics:** Definition, Physico-chemical factors altering biological performance of drugs with special emphasis on pH, partition hypothesis and dissolution rate. Physiological considerations including membrane, gastro-intestinal physiology and environment like presence of food, motility, etc. influence of formulation factors on absorption of drugs.
Bioavailability and bio-equivalence: concept and significance, methods of determination of bioavailability using blood level and urinary excretion data. Parameters used to evaluate bio-equivalence.
3. **Pharmaco-kinetics:** Absorption, distribution, metabolism and excretion of drugs, protein binding, pharmaco-kinetic parameters, determinations and their significance. Compartment kinetics: One and two compartment model, pharmacokinetics of single dose administration as applied to intravenous bolus and oral administration, curve fitting method of residuals as applied to plasma concentration profile for two compartment model.
Brief introduction to non-linear pharmacokinetics: concepts and applications, kinetics of multiple dosing and dosage regimen.
4. **Sustain release products:** Definitions and importance, types of S.R. products., design and development of oral and injectable S.R. products and evaluation of S.R products.
5. **Novel drug delivery systems:** Introduction and concepts, classification, basic back ground information on different types of novel delivery systems like occuserts, osmotic pumps, transdermal systems, implants and inserts. Introduction to the concept of targeted drug delivery.

PRACTICAL (50 hours)

1. Experiments to illustrate mechanisms of absorption and metabolism using isolated
2. organs.
3. Blood level profiles of selected drugs.
Experiments for determination of pharmacokinetics parameters and bioavailability based on salivary excretion and urinary excretion of selected drug formulations
4. using Human volunteers
5. Computation of pharmacokinetic parameters using computer programs.
Formulation of selected types of oral S. R. products and their evaluation by in-vitro dissolution profile.

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PH-404 INDUSTRIAL PHARMACY THEORY (50 hours)

1. **Capsules:** Advantages and disadvantages of capsule dosage forms, material and methods for production of hard gelatin capsules, size of capsules, formulations, methods of capsule filling and equipment involved, soft gelatin capsule shell and capsule content, importance of base absorption and minim/gram factors in soft capsules, quality control, stability testing and storage of capsule.
2. **Microencapsulation:** Types of microcapsules, importance of Microencapsulation in pharmacy, Microencapsulation by phase separation, co-acervation, multi-orifice, spray drying, spray congealing, polymerization, complex emulsion, air suspension technique, coating pan and other techniques. Evaluation of microcapsules.
3. **Tablets:** Formulation and manufacturing of different types of tablets, physics of tablet compaction, different types of tablet compression machinery and equipment employed. Evaluation of tablets.
4. **Parenteral products:** Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity and method of its adjustment, formulation techniques, types of containers and closures and their selection, facility design for parenteral manufacture as per GMP. Aseptic techniques, source of contamination and methods of prevention and design of aseptic area. Laminar flow bench services and maintenance, prefilling treatment, washing of containers and closures, preparation of solution and suspension, filling and sealing of ampoules, vials, infusion fluids, lyophilization and preparation of sterile powders, equipment for manufacture of SVP and LVP. Evaluation of parenterals.
5. **Ophthalmic products:** Requirements, formulation, methods of preparation, containers and evaluation.
6. **Packaging materials for pharmaceutical products:** Packaging components, types, specification and methods of evaluation, stability aspect of packaging, packaging equipments, factors influencing choice of containers, legal and other official requirements for containers and package testing.
7. Polymer science and application in formulation design.
8. GMP and validation and general aspect of plant design.

PRACTICAL (75 Hours)

1. Experiments to illustrate preparations, stabilization, physical and biological evaluation of pharmaceutical products like powders, capsules, tablets, parenterals, microcapsules, surgical dressing, etc.
2. Evaluation of materials used in pharmaceutical packaging.

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PH-405 MEDICINAL CHEMISTRY-II THEORY (75 hours)

1. Synthetic procedures of selected drugs, mode of action (biological and molecular basis wherever applicable), structure activity relationship including physicochemical properties of the following classes of drugs:
2. Steroids and related drugs: Steroids nomenclature and stereochemistry, androgens and anabolic agents, estrogens and progestational agents and adrenocorticoids, antihistamines, cyclo-oxygenase inhibitors, analgesics, antipyretics, anti-inflammatory agents, (NSAID), oxytocics, hypoglycaemic agents, thyroid hormones and antithyroid drugs. Antimetabolite concepts, sulfonamides, chemotherapeutic agents and urinary antiseptics, antiseptics and disinfectants. Drugs used in tuberculosis, leprosy, antibiotics, antiamoebic agents and antimalarials. Drugs used for trypanosomiasis and other protozoal diseases, anthelmintics, antifungal agents, antineoplastic and antiviral agents. Diagnostic agents, surface-active agents and other pharmaceutical aids. Immunomodulators. Cardiac drugs- antihypertensives, cardiotonic, antiarrhythmic, anticoagulant, antithrombotics, thrombolytics; antianginals, coronary vasodilator, hypolipoproteinemic drugs, diuretics and antidiuretics.
3. Concepts and brief introduction to gene therapy, nucleotidomimetics (antisense oligonucleotides), peptidomimetics.
4. Concepts and brief introduction of genetic engineering in medicinal chemistry.
5. Brief introduction to combinatorial chemistry.

PRACTICAL (75 Hours)

1. Workshop on stereo model use of some selected drugs.
2. Synthesis of selected drugs from the course content involving two or more steps of synthesis and their spectral analysis.
3. Establishing the Pharmacopoeial standards of drugs synthesized.
4. Determination of partition coefficient constant and molar refractivity of compounds for QSAR analysis.

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PH-406 PHARMACEUTICAL ANALYSIS-II THEORY (75 hours)

1. **Quality assurance:** GLP, ISO 9000, TQM. Quality review and quality documentation and ICH.
2. Regulatory control, regulatory drug analysis and interpretation of analytical data.
3. Validation, quality of equipment, validation of equipment and validation of analytical instruments.
4. **Chromatography:** Principles and techniques involving separation of drugs from excipients. The following techniques: TLC, HPLC, GLC, HPTLC, paper chromatography and column chromatography.
5. The theoretical aspects, basic instrumentation, elements of interpretation of data/spectra, and application of analytical techniques be discussed on potentiometric titrations (including Karl Fisher titration), conductometric titrations, polarography, amperometric titration, colorimetric titration, polarometry. UV and visible spectrophotometry, infrared spectrophotometry, brief introduction to nuclear magnetic resonance spectroscopy, brief introduction to – mass spectrometry, flame photometry, emission spectroscopy, atomic absorption spectroscopy, fluorimetry and thermal analysis including DSC and TGA.

PRACTICAL (75 Hours)

1. Quantitative estimation of at least 5 formulations containing single drug or more than one drug using instrumental techniques.
2. Estimation of Na and K and Ca ions using flame photometry.
3. IR determination of samples with different functional groups (-COOH, -COOR, -CONHR, -NH₂, -NHR, -OH, etc).
4. Workshop to interpret the structure of simple organic compounds using UV, IR, NMR and MS.
5. Exercises involving potentiometry, conductivity, polarography, fluorimetry and polarometry.

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PH-407 PHARMACOGNOSY-III THEORY (50 hours)

1. **Plant Biosynthesis:** Techniques employed in the elucidation of biosynthetic pathways, shikimic acid and isoprenoid pathways, biosynthesis of tropane, quinoline, iso quinoline and indole alkaloids, biosynthesis of steroidal and anthraquinone glycosides.
2. Introduction to primary and secondary metabolites
3. **Enzyme:** Introduction, general methods of isolation and purification of enzymes. Source, method of preparation, chemical nature and uses of papain, bromelaine, streptokinase, urokinase, hyaluronidase, asparaginase, diastase, pepsin, trypsin and pancreatin.
4. Plant bitters and sweeteners.
5. Role of medicinal and aromatic plants in national economy, importance and status of herbal medicines and cosmetics.
6. Novel medicinal agents from marine sources.
7. **Plant and culture-** types of cultures, nutritional requirements, growth, maintenance and applications of plant tissue culture in pharmacy.
8. Details of methods of isolation, method including industrial, identification, tests and estimation of: Quinine, ephedrine, cardiac glycosides, sennosides, diosgenin, glycyrrhizin, citrus bioflavonoids, rutin, andrographolides, guggul lipids, gymnemic acid and withanoides.
6. Introduction to Ayurvedic system of medicines: Prakriti -(Kaf, Vayu, and Pitta). Formulations: Arkas, Asavas, Arista, Avalehas, Bhasmas, churnas, ghritas, ghutikas, kvathas, lepams, malamas, pakas, satvas, suras, and tailas.
7. Importance of standardization of raw materials, extracts and formulations with examples. WHO guidelines for the assessment of crude drugs, extracts and medicines. Study of different methods for standardization of analytical techniques with special reference to HPLC, HPTLC and study of method used to detect and estimate the amount of heavy method in herbal formulation (Mg, Cu, Zn, As etc.). Determination of alcohol content in aristas, and Asawas.
8. Natural allergens, photosensitizing agents and fungal toxins.
9. Herbs as health foods.
10. An overview of plants used in the management of cancer, diabetes, inflammation, liver disorders, C.N.S., hypertension and AIDS.

PRACTICAL (75Hours)

1. Isolation and qualitative tests for different extracts of phytoconstituents representing different types of constituents.
2. Experiments in plant tissue culture.
3. Chemical evaluation of powdered drugs and enzymes.
4. Preparation and standardization of Ayurvedic formulations: Dashmularishta, Kumariasava, Ashwagangharishtha, Manjishthadikwath, Kanakasva, kutajarishta, punernavasva, maharasnadilwath, Amrutarishtha, mahasudershan churna, Shitopaladi churna, hingvasthak churna. Using chromatographic techniques.

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PH-408 PHARMACEUTICAL BUSINESS MANAGEMENT THEORY (50 hours)

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 and 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, columnar 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, bill of exchange, promissory notes and hundies and 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, inland and foreign trade, procedure of exporting and importing goods.
4. **Pharmaceutical Marketing:** Function, buying, selling, transportation, storage, finance, feedback, information, channels of distribution, wholesale, retail, departmental store, multiple shop and mail order business.
5. **Salesmanship:** Principles of sales promotion, advertising, ethics of sales, merchandising, literature and detailing. Recruitment, training, evaluation and compensation to the pharmacist.
6. **Market research:** Prerequisites, Basic information services.
7. **Material managements:** A brief exposure to the basic principles of material managements, purchase, stores and inventory control (eligibility, efficiency, evaluation, recruitment methodology, service conditions, termination, performance evaluation, etc.
8. **Production management:** A brief exposure of the different aspects of production management (visible and invisible) inputs, methodology of activities, performance, evaluation techniques, process-flow, process know-how and maintenance management.
9. Factors to be considered for ideal location to setup a pharmaceutical industrial unit.

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