M.Pharm Syllabus

DEPARTMENT OF PHARMACEUTICAL SCIENCES

SYLLABUS FOR MASTER OF PHARMACY

MPL 501: Advanced Pharmaceutical Drug Analysis

8 Credits (4-0-8)

The various topics stated below shall be dealt with in sufficient details giving specific examples of typical pharmaceutical substances from the official compendia wherever possible: UV-Visible Spectroscopy: Electromagnetic spectrum, UV-visible range, structural features, absorption of radiant energy, factors influencing absorption of radiant energy: Instrumentation — single-beam spectrophotometer, double-beam spectrophotometer, Assay methods, Applications in pharmaceutical analysis. Infrared Spectroscopy: Molecular vibrations, stretching vibrations, bending vibrations, vibrational frequencies, factors influencing vibrational frequencies, electronic effects, Instrumentation — Single-monochromator IR-spectrophotometer, experimental profile of IR-spectroscopy : Quantitative analysis, applications in the analysis of Pharmaceutical dosage forms, qualitative interpretation of IR-spectra, Recent advances in IR-spectroscopy, e.g. FT-IR, ATR, etc. Optical Rotatory Dispersion: Fundamental principles of ORD, Cotton-effect curves — their characteristics and interpretation, Octet rule and its applications, circular dichroism. Nuclear Magnetic Resonance Spectroscopy: The NMR-phenomenon *viz*. spinning nucleus, effect of an external field, precessional motion, precessional frequency, energy transition, chemical shift, ^{3}H-NMR (Tritium NMR-spectroscopy), ^{13}C-NMR-spectroscopy, 2D-NMR, interpretations of NMR-spectrum, instrumentation, applications in pharmaceutical analysis. Mass Spectrometry: Basic principles and brief outline of instrumentation, ion formation and types: molecular ion, meta-stable ions, fragmentation processes. Fragmentation patterns and fragment characteristics in relation to parent structure and functional groups; Mass spectrum, its characteristics, presentation and interpretation. Recent advances in MS, viz. GC-MS, chemical ionization MS and Fast Atom Bombardment Mass Spectroscopy. High Performance Liquid Chromatography (HPLC): Comparison of GC and HPLC, Instrumentation in HPLC, analytical, preparative, microbore columns, normal and reverse-phase packing materials, reverse-phase HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC- refractive index, photometric and electrochemical. Applications of these detectors. Size Exclusion Chromatography: Distribution coefficient, performance, materials, apparatus, applications in pharmaceutical analysis.Electrophoresis: Moving boundary electrophoresis, zone electrophoresis, continuous electrophoresis (preparative), isotadiphoresis, isoelectric focussing.

X-Ray Diffraction Methods: Elementary crystallography, X-ray diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffractometer — interpretation of data. Errors in Pharmaceutical Analysis and Statistical Validation: Introduction, classification of errors, viz. determinate and indeterminate errors, accuracy,

precision, minimizing systematic errors; Statistical Validation methods viz. Statistical treatment of finite samples, distribution of random errors, significant errors, comparison of results, method of least squares and criteria for rejection of an observation. Gas Chromatography (GC): Theory, Instrumentation- sample injector, columns, detectors, applications. High Performance Thin Layer Chromatography (HPTLC): Principles, instrumentation and applications. Thermal Analysis: Principles and applications of thermogravimetric analysis (TGA), Differential thermal analysis (DTA), and Differential scanning Calorimetry (DSC). Research Methodology and Literature Sources: Literature Survey, Citation of References, Presentation of Thesis, Abstract, Introduction, Research Envisaged, Experimental, Results, Discussion, Summary and Conclusion, Bibliography.
Practical: UV-Visible analysis of certain pure medicinal compounds: Their absorption bands and identification of structures e.g. Analgin, Paracetamol, Sulphamethoxazole, Ibuprofen, Ampicillin, Chloramphenicol, etc. Simultaneous estimation of two individual drug substances in some marketed combination formulations e.g. Trimethoprim & Sulphamethoxazole, Paracetamol and Ibuprofen, etc. Two-dimensional thin layer chromatography of mixture of amino acids, alkaloids, etc. Separation by electrophoresis of protein hydrolysates or mixture of amino acids. Comparison of two/three different analytical methods for certain pure drugs e.g. Salbutamol, Ephedrine, etc. Experiments based on HPLC. Structure elucidation of some known/unknown compounds. FT-IR/NMR/Mass spectroscopy of compounds. Case studies on Q.C. Laboratory & Analytical Reporting of Raw Materials, In-process and finished products. Any other relevant exercises based on theoretical aspects.

MPL 551 : Pharmaceutical Chemistry-II (Advanced Organic Chemistry)

8 Credits (4-0-8)
Chemical Kinetics & Thermodynamics- Kinetic and thermodynamic requirements for reaction, kinetic versus thermodynamic control. Non-kinetic and kinetic methods for determining mechanisms. Stereochemistry- Optical isomerism-Plane, centre & axis of symetry, chiral molecules-test and biological importance of chirality. Stereospecific and stereoselective nthesis. Resolution of racemic mixtures. Geometric isomerism- Resulting from double bonds, monocyclic componds, fused ring systems. Conformational isomerism-conformations in cyclic compounds. Reactive intermediates - structure, generation, stability and reactivity of carbocations, carbanions, carbenes, nitrenes and free radicals. Alkylation - Alkylation of nucleophilic carbon; enolates and enamines: generation & alkylation of enolates, dianions; oxygen vs. carbon as site of alkylation. Alkylation of aldehydes, esters, amides & nitriles. Enamines and imine anions. Pericyclic reactions- Molecular orbital symmetry, Woodward-Hofmann rules. Electrocyclic (Diels-Alder reaction) and sigmatropic reactions-Cope, Benzidine rearrangements. Cycloaddition. Rearrangements- Carbon to carbon migration-Wagner-Meerwein, Pinacol-pinacolone, Benzilic acid, Favorskii. C to N migration -Hoffmann, Curtius, Beckmann, Schmidt, Lossen. C to O migration- Bayer-

Villiger, hydroperoxides**.** Reduction reactions of carbonyl and other functional groups-Catalytic hydrogen- ation, reduction by Group III and Group IV hydride donors, disssolving metal reductions, reductive deoxygenation of carbonyl groups. Synthon approach- Concept, half-reactions, FGI, analysis of target molecule, synthetic strategies. Application to synthesis of benzocaine, propranolol, haloperidol, salbutamol and other drugs. Miscellaneous reactions. Electrophilic Aromatic Substitution –Nitration, halogenation, sulphonation, Friedel-Crafts reactions. Nucleophilic Aromatic Substitution –via diazonium ions. Electrophitic addition to C=C double bond- halogens, halogen halides, water. Carboxylic acids- formation from alcohols and aldehydes, interconversions of carboxylic acid derivatives. Reagents used in reduction & oxidation.

Practicals: Beckmann Rearrangement — Preparation of Benzanilide from Benzophenone, Benzophenone → Benzophenone-oxime → Benzanilide. Fisher-Indolization — Preparation of 2-Phenyl indole from acetophenone. Acetophenone→ Acetophenone phenylhydrazine → 2-phenylindole. Perkin's Reaction — Preparation of dibromocinnamic acid from Benzaldehyde Benzaldehyde → Cinnamic acid → Dibromocinnamic acid Fries rearrangement — Preparation of 2,5-Dihydroxy-acetophenone from Hydroquinone Hydroquinone → hydroquinone diacetate → 2,5-dihydroxy acetophenone. Conversion of *cis*-isomer to *trans*-isomer — Preparation of Diethyl fumarate from Maleic acid. Maleic Acid → Fumaric Acid → Diethyl fumarate Free Radical Coupling — Preparation of 2,2-Dihydroxy-1,1-binaphthyl from 2-naphthol 2-naphthol → Oxidised product →2,2-Dihydroxy-1,1-binaphthyl Solving problems based on QSAR Computer Aided Molecular Modelling

MPL 552: Pharmaceutical Chemistry-II (Advanced Medicinal Chemistry)

8 Credits (4-0-8)

Receptors- Types, structures and functions of receptors, signal transduction and G-proteins, theories of drug-receptor interaction, detailed study of adrenergic, cholinergic, histaminergic, dopaminergic and opiate receptors Nitric oxide- interplay of NO & biological systems. NO biosynthesis and cytotoxicity, NO synthetase inhibitors and their therapeutic significance. Autocoids-a) Enkephalins & endorphins b) Prostaglandins & other eicosanoids. Antiviral agents- DNA & RNA viruses, viral replication, retroviruses, strategies to design anti-HIV drugs, , antiviral drugs. Antineoplastic agents-molecular mechanism of cancer, oncogenes, alkylating agents, antimetabolites, antibiotics, natural products. Cardiovascular agents- Antiarrhythmics –basis of cardiac arrhythmias, classification of drugs used, mechanism of action, molecular features essential for antiarrhythmic activity. Antianginal agents-Pathophysiology of angina, classification and mode of action of drugs used, vasodilators. Antihypertensive agents-etiology of hypertension, basis of drug design, agents affecting sympathetic system, agents acting on smooth muscle, ACE inhibitors, diuretics. Antihyperlipidemic agents- classes of lipoproteins, hyperlipoproteinemia, development of antihyperlipidaemic agents, mode of action. Antifertility agents-methods of fertility control, steroidal and nonsteroidal antifertility agents, abortifacients.

Practical: Note: All the syntheses should be monitored by TLC and products confirmed by spectroscopy. Identification of compounds on the basis of spectroscopy- UV, IR, NMR and Mass. Quantitative estimation of functional groups. Quantitative estimation of Nitrogen in organic compounds. Synthesis of organic compounds of medicinal value such as- paracetamol, phenytoin, DEET, cinnamate esters, 8-hydroxy quinoline, quinoxaline etc. Resolution of racemic drugs by different methods such as preferential crystallization and column chromatography of diastereomeric salts.

MPH 553 : Pharmaceutical Chemistry-III (Chemistry of Natural Products)

8 Credits (4-0-8)

Mechanistic and biosynthetic approach to plant secondary metabolites: Acetate-malonate pathway (Biosynthesis of plant fatty acids, biosynthesis and oxidation of ricinoleic acid.) Polyketides (Biosynthesis of 6-methylsalicylic acid, petulin, penicillinic acid, griseofulvin, tetracyclines). Acetate-mevalonate pathway (biosynthesis of psoralen, gibberellic acid, cholesterol, conessine). Shikimic acid pathway (Biosynthesis of chlorogenic acid, cichoriin). Mixed biogenesis of plant products: Flavonoids and anthocyanins. Biosynthesis of alkaloids: Hyoscyamine, Morphine, Vindoline. Compounds derived from Amino acids: Colchicine, Cephalosporin C. Biosynthesis of porphyrins: Cobalamine. Study of the chemistry of natural products using degradative and synthetic methods and spectral techniques. Biological significance will also be discussed. Alkaloids: Quinine, Morphine, Reserpine. Coumarins: psoralen, xanthotoxin and umbelliferone. Flavonoids: Quercetin and Rutin. Steroids: Cholesterol, Vitamin D and Cardiac glycosides. Terpenoids: Zingiberene, Abietic acid and β-amyrin. Antibiotics: Chemistry of Penicillins, Cephalosporin, Polypeptides and Chloramphenicol. Antineoplastic agents obtained from Plants: Catharanthus alkaloids; Paclitaxel and derivatives; Podophyllotoxin, Etoposide and Teniposide. Plant hormones including brassinosteriods. Marine products with therapeutic potential.

Practical: Isolation and characterization of medicinally active constituents e.g. Eugenol from clove, Curcumin from Turmeric, Hesperidin from Orange Peel, Glycyrrhizin from Glycyrrhiza, Piperine from Black Pepper, Trimyristin and Myristicin from Nutmeg, Pectin from Orange Peel, Ascorbic acid from Lemon, Sennoside from Senna, Menthol from Peppermint oil. sitosterol from edible oils, Glycosides, Alkaloids, Terpenoids from natural sources, Degradation reactions of natural products and their identification by micro-TLC, qualitative tests and spectroscopic methods viz. Atropine, caffeine, ephedrine and nicotine. Paper chromatography, electrophoresis of amino acids derived from plant sources.

MPL 601 Pharmaceutics–I (Product Development)

8 Credits (4-0-8)

Preformulation :Objectives, methodology, physico-chemical parameters *viz*. pKa and solubility, partition coefficient, vapour pressure, polymorphism, surface characteristics, compatibility tests, applications of solubility parameters in the development of solid, oral liquid and parenteral dosage forms. Pilot plant scale up techniques : Significance, scale-up techniques for tablets, capsules and liquid orals (involving specific considerations e.g. formula, equipment, product uniformity, stability, processing, physical layouts, personnel required etc.).

Production management & documentation : GMP considerations, quality assurance and quality control, process and equipment validation for tablets and parenterals, basic principles of materials management and cost control, ISO-9000 series, salient features, intellectual property rights, patent application procedures. Optimization procedures in formulation and processing : Optimization parameters, classical techniques, statistical design and applied optimization methods. Packing materials : Selection and evaluation of materials for containers and closures, pharmaceutical specifications, tests and standards for packing components, Tamper evident packages. Drug stability : Shelf-life determination, overages, accelerated stability testing, effect of packaging components on stability, factors affecting stability of pharmaceutical products. Dosage forms:Theoretical and practical aspects in the manufacture of different dosage forms- Solid dosage forms-tablets, capsules, microcapsules. Liquid dosage forms-suspensions, emulsions-multiphase and microemulsions; solubilization. Parenteral dosage forms-small and large volume parenterals.

Practical: Accelerated stability studies on formulations and pure drugs with respect to: Temperature dependence, Effect of pH and buffers, Effect of humidity. Determination of rate and order of decomposition of drugs, such as: Aspirin, Ampicillin, Ascorbic acid. Preparation and evaluation of gels containing two different bases. Study of effect of various additives (*viz*. Binders, disintegrants) on the properties of tablets. Formulation and evaluation of the stability of reconstituted drug syrups of: Amoxycillin, Ampicillin etc. Formulation and evaluation of semi-solid dosage forms using different bases and drugs of current interest. Preparation and comparative evaluation of marketed products.

MPL 602 Pharmaceutics–II (Biopharmaceutics & Pharmacokinetics)

8 Credits (4-0-8)

General Principles: Drug Absorption, Distribution, Metabolism & Excretion. Factors affecting these processes. Concepts of Bioavailability & bioequivalence. Review of Compartment Approaches : Terminology, Kinetics of single and multiple dose administration, one and two compartment models, basics of Pharmacokinetics and Chronopharmacokinetics. Non-compartmental Pharmacokinetics: Model independent approaches and their advantages, stochastic approach and statistical moment theory, determination of AUC, AUMC, MRT, MDT, MTT and MAT. Advanced techniques like log-trapezoidal, spline, Lagranges, PTTO and hybrid approaches, Computation of statistical moments from plasma and urine data, pharmacokinetic evaluation of Cl, Vd and $t_{1/2}$. Systems theory, theory of Response Mapping Operator (RMO), applications. Linear Recirculation Models. Non-Linear Pharmacokinetics: Definition, significance and application, determination of non-linearity, computation of non-linear pharmacokinetic parameters (Km & Vm) by Michaelis-Menten kinetics. Clinical Pharmacokinetics: Kinetics of pharmacological response, explanation of clinical response via pharmacokinetics. Monitoring of Plasma concentration of drug during clinical use, clinical relevance of kinetic studies, turnover concepts. Individualization of dosage regimen, reasons of variability – genetics, age, weight, disease, drug interaction , etc. Pharmacokinetc & Pharmacodynamic Models: basic concepts, applications and limitations with respect to classical

compartmental approaches, inter species scaling, integrated PKPD models. *In Vitro –InVivo Correlations* :Drug dissolution, principles and methodology, different methods of *in vitro-in vivo* correlation, their applications and limitations. Controlled release dosage forms: Bioavailability and pharmacokinetics of oral, parenteral, ocular, transdermal CRDF and IUDs. Computer Applications and Pharmacokinetics : Introduction, strategy for model building, selection and application of suitable pharmacokinetic, statistical and variance models, function minimisation, iterative and noniterative techniques and weighting schemes for nonlinear regression. Critical evaluation of computer fits and computer use in ADME. Literature review on computer software for pharmacokinetics, study of some computer software like- PC-NONLIN, NONMEM/NM-WIN, MicroPharm-K, TOPFIT etc.

Practical: Effect of polymorphism on solubility and dissolution rate. Comparison of dissolution rates of different marketed products. Determination of bioavailability from blood level and urinary excretion data. Protein binding of drugs. Study of drug absorption through everted rat-gut method : influence of different variables like pH, and drug concentration. *In situ* absorption of drugs in laboratory animals. Calculation of AUC, Ka, Ke, $t_{1/2}$, Cmax, Tmax and Bioequivalence from the data obtained/provided. *In vitro- in vivo* correlations.

MPL 603 Pharmaceutics–III (Novel Drug Delivery Systems)

8 Credits (4-0-8)

Fundamentals of Novel Drug Delivery: Rationale of sustained/controlled release(CR), physicochemical and biological factors influencing design and performance of CR products. Pharmacokinetic and Pharmacodynamic basis of NDDS. Bioavailability assessment of CR systems. Regulatory requirements. Theory of mass transfer. Fick's law and its application in NDDS. Triggered, pulsed and programmed drug delivery systems. Polymers in CR: classification, properties biocompatible & biodegradable polymers. Modeling of drug release from porous polymer; drug release from non-porous and hydrophobic polymers. Diffusional release and dissolution controlled release from monolithic devices, microporous systems. Oral Controlled Drug Delivery Systems: Oral systems based on dissolution, diffusion and other mechanism. pH control on exchange resins, gel diffusion, osmotic pumps. Hydrodynamically balanced system, Modulation of GIT transit. Mucosal Drug Delivery System: Mechanism of trasmucosal permeation, mucous membrane model, buccal, nasal, pulmonary, rectal and vaginal Drug Delivery systems, Intra Uterine Devices. Ocular Drug Delivery Systems: Fabrication and application of ocuserts. Parenteral Drug Delivery systems: Biopharmaceutical considerations. Solutions, suspensions and emulsions. Implantable therapeutic systems, approaches to develop implants. Transdermal Drug Delivery Systems: Drug absorption through skin, basic components of TDDS, types and techniques for development and evolution. Iontophoresis, Sonophoresis and electroporation, Drug permeation enhancers. Multiple emulsion and Micro emulsion: Multiple w/o/w emulsions as drug vehicles- introduction, composition of multiple emulsion and stability, mechanism of transport of solutes, in vivo studies. Micro emulsion- introduction, structure of micro emulsions, solubilisation and formulaton, transport properties and

applications. Biochemical and Molecular Biology Approaches to CDDS: Microparticulate Drug Carriers- structural aspects, preparation, characterisation, evaluation and applications of Liposomes, Nanoparticles, microspheres etc. Other vascular systems- general aspects and applications of niosomes, crythrosomes, pharmacosomes, aquasomes and supramolecules. Monoclonal antibodies- preparation and applications. Absorption of proteins and peptide drugs: Consideration in the delivery of proteins and peptides, stability, membrane barriers, delivery systems for proteins and peptides, toxicity aspects; Enzymes and enzyme immobilization. Recent trends in vaccine and vaccine delivery systems.

Practical: Preparation of various polymer films containing different drugs and studies of the film characteristics and release pattern. Study of the diffusion of drugs through various polymer membranes. Preparation and evaluation of microcapsules by different microencapsulation techniques. Preparation of released erythrocytes from blood, loading of various drugs and study of the released pattern. Preparation and evaluation of wax embedded microspheres of diclofenac sodium and theophylline. Preparation of albumin microspheres and their evaluation *viz*. Particle-size characterization, flow properties and release study. Studies on *in vitro* dissolution of various sustained release products — preparation and comparison with marketed products.

MPL 701 Pharmacology-I (Advanced Pharmacology)

8 Credits (4-0-8)

Principles of Clinical Pharmacology : Definition, scope, development of clinical pharmacology, drug receptors, mechanism of action, drug biotransformation, drug administration in special situations like geriatrics, pediatrics, pregnancy and lactation. Autonomic Pharmacology: Parasympathomimetics, sympathomimetics, parasympatholytics, sympatholytics, ganglion and neuromuscular blockers. Drug Therapy of Cardiovascular Disorders: Hypertension Congestive Heart Failure, Angina, Arrhythmia, Hyperlipidemia. Drug Therapy of GIT disorders: Peptic Ulcers, emesis, diarrhoea and constipation Antineoplastic agents: Classification, mode of action, therapeutic applications. Drug Therapy of Rheumatoid arthritis and gout: Mechanism of inflammation, COX- I and COX-II inhibitors. Chemotherapy of Infectious Diseases: Antibacterial drugs- sulfonamides, quinolones, penicillins, tetracyclines, chloramphenicol, cephalosporins, aminoglycosides, antiviral, antifungal and antiprotozoal chemotherapy, drug therapy of helminthiasis, tuberculosis and leprosy, development of drug resistance. Bioassays: Principles, Types, advantages of bioassays.

Practical: Bioassays of histamine using gunea pig/rat ileum. Bioassay of serotonin using rat fundus. Bioassay of oxytocin using rat uterus. Bioassay of acetylcholine using frog rectus abdominis muscle preparation. Determination of pA2 value. Screening of memory enhancers.

MPL 702 Pharmacology-II (Recent Trends in Pharmacology)

8 Credits (4-0-8)

Drug Therapy of Alzheimer's disease -Drug Therapy of Epilepsy, Depression, Psychosis, Anxiety, Migraine, Parkinsonism. Advances in Receptor Pharmacology (Adrenergic, Cholinergic, 5-HT, GABAergic, Histaminic), Ion Channels Recent advances in treatment of diabetes mellitus. Recent advances in treatment of asthma. Recent advances in Calcium channel blockers, Potassium channel openers, Angiotensin Converting Enzyme Inhibitors. Immunosuppressive Agents. Platelet Activating Factor and their antagonists. Essential Drugs

Practical: Isolated heart preparation using Langendorff Heart Preparation. Screening of drugs using rota-rod, photoactometer, Cook's pole-climbing apparatus, analgesiometer, convulsiometer, elevated plus maze. Screening of anti-inflammatory agents and antidepressants.

MPL 703 Pharmacology-III (Pharmacological Screening of drugs)

8 Credits (4-0-8)

Study of animal models for screening of following categories of drugs : Analgesics, Anti inflammatory, Local Anesthetics, Antianxiety, Antidepressant, Antipsychotics, Anticonvulsant, Anti Parkinsonism, Antihypertensives, Antidiabetics, Anti-fertility, Anti -Alzheimer's disease

Practical: Standardization of procedure/technique/model related to research project. Toxicity Testing of Drugs. Evaluation of anti-inflammatory, anti-diabetic and anti-Parkinsonism drugs, antidepressant and memory enhancing drugs.

MPL 801 Pharmacognosy-I (Advanced Pharmacognosy)

8 Credits (4-0-8)

Comparative Phytochemistry: Principles of Taxonomy, Study, development, significance of chemotaxonomy with special reference to phytoconstituents viz. Alkaloids, glycoside, terpenes, flavonoids, etc. Factors affecting plant drug cultivation: Characteristics of soil, exogenous and endogenous factors essential for plant growth. Fertilizers and their management. Pest Management. Herbal Pesticides & Insecticides. Plant Tissue Culture: History of Plant tissue culture, totipotency, Ingredients used in plant tissue culture media. Callus Culture, Suspension cultures, meristem culture, protoplant cultures, haploid cultures and immobilization, organogenesis. Regenaration of plants from tissue culture. Biosynthetic potential of tissue culture and factors affecting production of secondary metabolites by tissue culture technique. Application of plant tissue culture in Pharmacognosy/ production of phytopharmaceuticals.

Practical: Preparation and Sterilization of Nutrient media, plant cell culture, callus culture. Preparation of Herbarium Identification of Plant constituents with chromatographic techniques viz. Thin Layer, Preparative TLC, Paper, HPLC.

MPL 802 Pharmacognosy-II (Herbal Drugs Development)

8 Credits (4-0-8)

Herbal sources of food supplements, Bioavailability enhancers, plant bitters & sweeteners. Herbal Cosmetics: Identification, collection and chemical nature of the natural products used in: Hair care, dandruff, dyeing, Skin care, anti-wrinkles & anti-aging, leucoderma, Scabies Anticancer Herbal drugs, Herbal Extracts and Their sources, Herbal production, formulation & Development: Introduction, Volume, trade, commerce, resources, status in India and abroad, Traditional versus modern system. Regulatory requirements for manufacture and distribution of herbal formulations, Standardization of Herbal Drugs: Quantitative Pharmacognosy, Modern Instrumental Techniques, Biological response measurements.

Practical: Standardization of Herbal Drugs by: Morphology, Histology, Quantitative microscopy, Physical constants – Sp. Gravity, ash value, moisture content, extractive values, optical rotation. Preparation of simple herbal cosmetics like, hair oil, shampoos, creams.

MPL 803 Pharmacognosy-III (Characterization of Plant Constituents)

8 Credits (4-0-8)

Methods of investigation of biogenetic pathways. Basic principles involved in the phytochemical and biological screening of plant drugs in : Analgesics, anti-inflammatory, cardiotonic, hypoglycemic drugs and plant immodulators

Extraction, Isolation and characterization by chemical and spectral means of various active principles having edicinal, industrial and clinical importance from the following categories: Alkaloids, glycosides, steroids, antibiotics, vitamins, terpenoids, lipids, volatile oils, coumarins and photosensitizing agents

Practical: Extraction, isolation and purification of following phyto-pharmaceuticals, Caffiene, quinine, piperine, Sennoside, Hesperidine, rutin, vasicine, curcumin, atropine. Data interpretation of compounds isolated above, Solubility, melting point, optical rotation, U.V. and I.R. Chromatography by TLC of compound isolated, where standard available.

MPL 511 THERAPEUTIC DRUG MONITORING

4 Credits (4-0-0)

Introduction to Therapeutic drug monitoring : Definition and introduction, historical background, Indication for therapeutic drug monitoring, monitoring plasma drug levels, clinical application of therapeutic drug monitoring. Role of clinical pharmacist in therapeutic drug monitoring. Techniques used in Therapeutic drug monitoring : Overview of physicochemical methods used for therapeutic drug monitoring. Techniques : Physical Methods : Detailed study of different chromatographic techniques like High Performance Liquid Chromatography (HPLC), High Performance Thin Layer, Chromatography (HPTLC), Gas Chromatograph, (GC), Counter Current Chromaography (CCC) Immunoassays : Detailed study of following immunoassays : Radio-Immunoassay (RIA), Enzyme Multiplied Immunoassay, Technique (EMIT), Fluorescence Polarisation Immunoassay (FPIA), Enzyme Linked Immunosorbent

Assay (ELISA), RPIA, Apoenzyme Reactivation Immunoassay system (ARIS), Nephalometric Inhibition Immunoassay (NIIA), Substrate Labeled Fluoroscence Immunoassay (SLFIA), Prosthetic Group Labeled Immunoassay (PGLI). Criteria for selection of method for Therapeutic Drug Monitoring : Properties of drug molecule such as chemical structure, molecular weight, pka values, melting and boiling point, drug solubility, concentration range of compound. Characteristic of method like level of precision and accuracy required, complexity of the sample, number of samples to be analysed, time required for analysis, specificity and sensitivity of the method, cost of the method. Importance of Therapeutic Drug Monitoring with reference to Adverse Drug Reactions and Drug interaction. Variation of Clinical Laboratory Tests due to drugs : Tests : Serum creatinine, Blood Urea Nitrogen, Plasma Glucose, Creatine Kinase, Phosphatases, Amylase, Bilirubin, Serum Proteins, Globulin, Complete Blood Count and Differential Blood Count.Therapeutic Drug Monitoring of specific drugs : Clinical pharmacokinetics, general guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reaction and drug interactions, clinical interpretation, technique used for estimation and importance of : Digoxin, Valproic Acid, Gentamicin, Procainamide, Lidocaine, Phenytoin, Lithium, Phenobarbitone, Theophylline, Quinidine. Cytotoxic and Hepatotoxic Drugs : Classification of cytotoxic drugs, mechanism of action, pharmacokinetics, adverse drug reaction, potential drug interactions, importance and necessity of therapeutic drug monitoring of cytotoxic and various hepatotoxic drugs. Bioequivalence and Therapeutic Equivalance : Definition and concept, terminology involved *in vivo* bioequivalance criteria and issues, study design for assessment of the bioavailability and bioequivalence, statistical criterias, regulatory requirements, type of bioequivalence studies, Pharmacodynamic models for bioequivalence, fundamentals of integrated PK/PD in models and importances of bioequivalence. Clinical case reports and Discussion

MPL512 DRUG DESIGN

4 Credits (4-0-0)

Approaches to drug design, method of variation, biochemical and physiological approaches. Lead compound - Search & Optimization **:** Search of lead compound from natural products and other sources, selection of test compounds. Methods of lead optimization – synthesis of analogs, variation of substituents, extension of structure, ring versus chain structures, bioisosterism, ring contraction and expansion. Case study of Cimitidine and Oxamnioquine. Quantitative Structure Activity Relationship (QSAR) **:** Physicochemical parameters – hydrophobicity, electronic and steric parameters, calculation of parameters such as molecular connectivity and molar refractivity. Hansch analysis, Free-Wilson analysis, Craig plot, Topliss scheme Prodrugs : Objectives of Prodrug Design **–** increasing bioavailability, improving membrane permeability, prolonging activity, reducing side effects, removing undesirable properties. Prodrugs from different functional groups-carboxyl, amino, hydroxyl etc. Enzyme Inhibitors : Theory of enzyme action and inhibition, types of inhibition-reversible

and allosteric inhibition, medicinal importance of enzyme inhibitors. Drugs through microbial transformation. Combinatorial chemistry, solid phase synthesis, Solution phase synthesis, deconvolution techniques and applications of combinatorial chemistry.

MPL 513 STERILE PRODUCTS TECNOLOGY

4 Credits (4-0-0)

History of parenteral medication, development of parenterals, packaging, types of preparations. Vehicles, added substances for parenterals, sterile suspensions and ophthalmic solutions. Environmental control, personnel, packaging components, product preparation, control and labeling. Parenteral admixtures and incompatibilities. Fundamentals of fluid and electrolyte therapy. Radiopharmaceuticals used in parenterals. Parenteral devices such as syringes, cannula, catheters, hazards associated with parenteral therapy.

MPL 514 QUALITY ASSURANCE

4 Credits (4-0-0)

Interpretations of current good manufacturing regulations. Auditing function in the Total control of Quality, process validation and control of components, containers and closures. Production and process controls, Packaging and labelling controls, Laboratory controls. Records and Reports. Returned and Salvaged Drug products. Repacking and Re-labelling. Problem Analysis and Corrective Action Report. Quality control of Biologicals-International Biological Standards. Quality Control of Antibiotics. Evaluation of Sustained Release Products.