INSTITUTE OF CHEMICAL TECHNOLOGY

(Deemed to be University under section 3 of the UGC Act 1956)

Detailed Syllabus for First Year M. Pharm Drug Delivery Technology

Sr. No.		Hrs
Core Subjects		
1.	**PYT 2106– Physical Methods of Analysis (50 marks) 3hr./week**	
	Fourier Transform Infrared Spectroscopy: Molecular Vibrations, Frequency shifts associated with structural changes; Basic theory of FTIR spectroscopy, inteferogram, digitization of interferogram, data points collection; Instrumentation and advantages of FTIR spectrophotometry; Qualitative and quantitative analysis using infrared spectrophotometry.	
	Ultraviolet and Visible Spectrophotometry: Electronic transition, spectrum, shift of bands with solvents, isolated double bonds, conjugated dienes, carbonyl compounds, aromatic and heteroaromatic compounds; Application in pollution control and chemical industry.	
	Nuclear Magnetic Resonance: Basic principle of NMR phenomenon, relaxation processes, spin-spin interaction, chemical shifts, interpretation of NMR spectra, correlation-hydrogen bonds to carbon and other nuclei; Instrumentation-Continuous and pulsed NMR, carbon- 13NMR.	
	X-ray Diffraction: Crystal geometry and structural determination; Bragg law of X-ray diffraction, powder method; X-ray spectrometers-wide and small angle diffractrometers; Chemical analysis by X-ray diffraction.	
	Particle Size Analysis: Particle size, sampling, conventional techniques of particle size measurement, light scattering particle size measurement by light scattering techniques; Dynamic light scattering (DLS), fibre optic dynamic light scattering (FDLS).	
	Chromatography: Basic theory of separation, efficiency, resolution; Liquid chromatography, high performances liquid chromatography; Gas chromatography-columns and detectors; Qualitative and quantitative analysis.	
	Mass spectroscopy: Basic principle, ionization of a molecule on electron impact, fragmentation processes in organic compounds, interpretation of mass spectra, molecular weight, molecular formula; Instrumentation-different types of ionization sources and magnetic analyzer.	
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2.	**PHT 2102– Drug Delivery Systems – I (50 marks) 3hr./week**	
	Design, development, manufacture and evaluation of the following:	
	Oral Drug Delivery Systems: Osmotic DDS, Ionexchange controlled DDS, Hydrodynamically balanced DDS including recent advances	8
	Mucosal DDS: Physiological basis of mucosal delivery with reference to oral	7

	mucosal, nasal, vaginal and rectal routes. Bioadhesion and bioadhesive polymers, DDS for mucosal administration.	
	Transdermal DDS: Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to manufacturing equipment components and evaluation. Iontophoretic and Sonophoretic DDS.	7
	Ocular DDS –Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation.	4
	Dental DDS: DDS for oral conditions, and dental care and therapy including periodontal disease, dental caries etc.	2
	Veterinary DDS – Physiological basis, devices and formulation	2
	• Handbook of Pharmaceutical Controlled Release Technology, edited by Donald Wise Marcel Dekker, 2000. • Oral Mucosal Drug Delivery by Michael J. Rathbone (Editor) Marcel Dekker; (June 1996) • Bioadhesive Drug Delivery Systems Fundamentals, Novel Approaches, and Development Series Volume: 98 Edited By: Edith Mathiowitz; Don E. Chickering; Claus-Michael Lehr 1999. • Nasal Systematic Drug Delvery Series Volume: 39 Yie W. Chien; Kenneth S. E. Su; Shyi-Feu Chang 1989. • Transdermal Drug Delivery by Richard H. Guy (Editor), Jonathan Hadgraft (Editor), Michiko Elizabeth Barro Yusa Marcel Dekker; 2nd edition (January 2003) • Electricity Assisted Transdermal and Topical Drug Delivery by Ajay K. Banga, Tayior and Francis; (September 1998) • Mechanisms of Transdermal Drug Delivery Volume: 83 Edited By: Russell O. Potts; Richard H. Guy. 1997. • Transdermal Controlled Systemic medications by Y. W. Chien, Marcel Dekker, 1987 • Biopharmaceutics of Ocular Drug Delivery by Peter Edman CRC Press: (November 18, 1992) • Ophthalmic Drug Delivery Systems, edited by Ashim Mitra, Marcel Dekker, 1993. • Novel Drug Delivery Systems Second Edition, Revised and Expanded Series Volume: 50 Yie W. Chien, 1991 • Controlled Release Veterinary Drug Delivery by Michael J. Rathbone (Editor), Robert Gurny (Editor)Elservier Science; 1st edition (July 1, 200) • Polymeric Drugs and drug Delivery Systems Raphael M. Ottenbrite and Sung Wan Kim, eds. Technomic, 2001. • Controlled Drug Delivery – Foudamentals & applications by J. R. Robinson-2nd edition – Marcel Dekker, 1987 • Dermatological Formulations: Percutaneous absorption by Brian W. Barry.	
3	**PHT 2103- Advanced Pharmaceutics (50 marks) 3hr./week**	
	Polymers: Introduction to methods of polymerization of homo and hetero polymers.	10

	Mol.weight of polymers, flow characteristics of polymers. Crystallinity and phase transitions, polymers degradation & stabilization, polymer properties and their evaluation, Polymers for controlled release Bioadhesive polymers, stimuli sensitive polymers. Biodegradable polymers, Biodegradation of polymers, enzymatically degradable bonds in synthetic polymers.	
	Pharmaceutical Preformulation design and methodology	2
	ICH guidelines for stability evaluation	2
	Pelletization and design and evaluation of multiparticulate oral systems	3
	Physics of Compression & Compaction	2
	Validation Process and Equipment in formulation development	4
	Dissolution testing, medium selection and validation of dissolution apparatus	5
	Statistical Designs including Factorial and other approaches. Introduction to Artificial Neural Networks	2
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4	**Elective-I (50 marks) 3hr./week**	
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5	**Elective-II (50 marks) 3hr./week**	
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6	**PHT 2101– Research Methodology (50 marks) 3hr./week**	
	<u>Research</u> 1. Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) – Objective of research- 2. Literature survey – Use of Library, Books, & Journals – Medline – Internet, getting patents and reprints of articles as sources for literature survey. 3. Selecting a problem and preparing research proposal for different types of research mentioned above. 4. Methods and tools used in Research • Qualitative studies, Quantitative Studies • Simple data organization, Descriptive data analysis • Limitations and sources of Error • Inquiries in form of Questionnaire, Opinionnaire or by interview • Statistical analysis of data including variance, standard deviation, students 't' test and annova, correlation data and its interpretation, computer data analysis, 5. Documentation • "How" of Documentation • Techniques of Documentation • Importance of Documentation • Uses of computer packages in Documentation 6. The Research Report / Paper writing / thesis writing	

	• Different parts of the Research paper 1. Title – Title of project with author's name 2. Abstract – Statement of the problem Background list in brief and purpose and scope 3. Key-words- 4. Methodology-Subject, Apparatus / Instrumentation, (if necessary) and procedure 7. Results – tables, Graphs, Figures, and statistical presentation 8. Discussion – Support or non- support of hypothesis – practical & theoretical implications, conclusions 9. Acknowledgements 10. References 11. Errata 12. Importance of spell check for Entire project 13. Use of footnotes	
	<u>Presentation (Specially for oral)</u> • Importance, types, different skills • Content of presentation, format of model, Introduction and ending • Posture, Genstures, Eye contact, facial expressions stage fright • Volume- pitch, speed, pauses & language • Visual aids and seating • Questionnaire	
	<u>Protection of patents and trade marks, Designs and copyrights</u> • The patent system in India – Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents • Advantages • The Science in Law, Turimetrics (Introduction) • What may be patented • Who may apply for patent • Preparation of patent proposal • Registration of patent in foreign countries and vice-versa	
	<u>Sources for procurement of Research Grants</u>	
	<u>Industrial- Institution Interaction</u> - Industrial projects – Their feasibility reports	
	• Research in Education – Johan V. Best James V. Kahn • Presentation skills- Michael Halton- Indian Society for Institute Education • A Practical Introduction to copy right – Gavin Mcfarlane • Thesis projects in Science and Engineering – Richard M. Davis • Scientists in legal system – Ann labor science • Thesis and Assignment writing – Jonathan Anderson • Writing a technical paper- Donald Menzel • Effective Business Report writing – Leland Brown	

	• Protection of Industrial property rights- Purushottam Das and Gokul Das • Spelling for the million – Edna furmess • Preparing for publication – King Edwards Hospital fund for London • Information technology – The Hindu speaks • Documentation – Genesis & Development 3792 • Manual for evaluation of Industrial projects – United Nations • Manual for the preparation of Industrial feasibility studies	
7	**PHT 2105– Drug Delivery System – II (50 marks) 3hr./week**	
	Design, development, manufacture and evaluation of the following:	
	Parenteral DDS: CR Injectables, implants etc. development and evaluation	5
	Colloidal DDS: Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, sub micron emulsions, liposomes, niosomes, and other vesicular DDS, nanoparticles, their design and development into final dosage forms, issues and consideration	8
	Peptide and protein based DDS: Chemistry and special features of peptide and protein molecules, stability, analysis, Formulation and evaluation Barriers to peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene based DDS.	5
	Pulmonary DDS – Physiological basis and formulation considerations. Design of Pressurized aerosols, Dry powder DDS, Devices for administration and evaluation.	4
	Targeted DDS: Concept of drug targeting, basis for drug targeting both active and passive. Monoclonal antibodies another markers, design of targeted DDS.	4
	Intrauterine Devices, Intravaginal drug delivery system	2
	Miscellaneous DDS: DDS for orthopedic applications Intra coronary stents. (medicated and non-medicated)	2
	• Sterile Dosage Forms: Their Preparation and Clinical Application by Salvatore J., M. S. Turco, Salvatore Turco Lea & Febiger; 4th edition (January 1994) • Parentral Quality Control Sterility, Pyrogen, Particulate, and Package Intergrity Testing: Third Edition, Revised and Expanded Series Volume: 125 Michael J. Akers; Dan Larrimore; Dana Morton Guazzo 2002. • Colloidal Drug Delivery Systems by Jorg Kreuter (Editor) Marcel Dekker; 1st edition (July 15, 1994) • Controlled Release Gel Formulations for Mucosal Drug Delivery edited by Mattias Paulsson Uppsala Univesitet; (December 2001) • Colloidal carriers for controlled drug delivery and targeting: modification, characterization, and in vivo distribution by Rainer H. Muller. Wissenschaftliche Verlagsgesellschaft CRC Press; (1991). • Submicron Emulsions in Drug Targeting and Delivery (Drug Targeting and Delivery) by Simon Benita (Editor) Taylor & Francis; (October 1, 1999) • Multiparticulate Oral Drug Delivery. (Editor), Marcel Dekker; 1st edition (June 15, 1994)	

	• Trends and Future Perspectives in Peptide and Protein Drug Delivery (Drug Targeting and Delivery) by Mitsuru Hashida, Yutaka Mizushima (Editor), V. Lee (Editor). Taylor & Francis; (February 1, 1995) • Peptide & Protein Drug Delivery by Frokjaer Munksgaard International Publishers; 1st edition (October 1998). • Peptide and Protein Drug Delivery by Vincent H. L. Lee (Editor) Marcel Dekker, (November 19, 1990) • Protein Formulation and Delivery Series Volume: 99 Edited By: Eugene McNally 1999. • Drug Delivery to the Lung by Hans Bisgaard (Editor), Chris O'Callaghan (Editor), Gerald C. Smaldone (Editor) Marcel Dekker; 1st edition (January 15, 2002) • Trends and Future Perspectives in Peptide and Protein Drug Delivery (Drug Targeting and Delivery) by Misturu Hashida, Yutaka Mizushima (Editor), V. Lee (Editor) • Liposomes in Biomedical Applications (Drug Targeting and Delivery) by Pang N. Shek (Editor) Taylor & Francis; (September 1, 1995). • Drug Targeting Technology, Physical-Chemical-Biological Methods Series Volume: 115 Edited By: Hans Schreier, Marcel Dekker 2001. • Handbook of Biodegradable Polymers (Drug Targeting and Delivery) by A. J. Domb (Editor), Joseph Kost (Editor), David M. Wiseman (Editor) 2001 • Bio-related Polymers and Gels: Controlled Release and Applications in Biomedical Engineering by Teruo Okano (Author) Academci Prss; 1st edition (May15, 1998) • Smart Polymers for Bioseparation & Bioprocessing by Bo Mattiasson (Editor), Igor Galaev (Editor), Kenneth Katzer, Harwood Academic Pub; 1st edition (June 15, 2002) • Cordonary artery Stenting ed. S Golberg, Cooper Synergy Blackwell, 2001	
8	**PHT 2106– Models for Drug Delivery Systems Evaluation (50 marks) 3hr./week**	
	Pharmacodynamic models for evaluation of DDS containing drugs of various categories eg. Cardiovascular agents; Antidiabetic; Antiinflammatory; Antiepileptic; Anticancer; Hepatoprotectives; Analgesics; Antistress; Antiasthmatic and Antitussives etc.	12
	In vitro cell culture techniques for evaluation of drug permeation from DDS including isolation maintenance of cell lines, culturing monolayers, evaluation of drug transport.	6
	In vitro / ex vivo models for evaluation of Drug absorption	3
	In vitro cytotoxicity evaluation using cell cultures and techniques such as MTT assay, Dye uptake etc.	3
	Toxicity testing: In vitro: In vitro toxicity testing and its application to safety evaluation, General perspectives, in vitro toxicity trends and issue, Ocular and cutaneous irritation,	6

	Validation of In vitro toxicity tests. Acute, sub acute and chronic toxicity testing – Biochemical basis of toxicity, Design of toxicological studies, Quality assurance in toxicology studies, Toxicity by routes – Parental, oral, percutaneous and inhalation, Target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity. Regulatory status- Ethical, moral and professional issues.	
	• Bioassay Techniques for drug Development, Atta Ur Rahman, M. Iqbal Choudhary, William J. Thomsen • In vitro Methods in Pharmacuetical Research, Edited by J. V. Casterll, M. J. Gomer, Lechon, Academic Press. • In Vitro Toxicity Testing by John M. Fraizer • General and Applied Toxicology by Bryan Ballantyne, T. Marrs & P. Turner.	
9	**PHT 2107– Targeted Drug Delivery (50 marks) 3hr./week**	
	Introduction to Targeted Drug Delivery Concept of drug targeting, basis for drug targeting, need for targeting, the physicochemical and physiological basis of targeting, RES	6
	Receptor mediated drug targeting	6
	Colon targeting approaches and DDS	4
	Targeting to the brain	3
	Targeting in cancer and infectious diseases	8
	Ligands for targeted delivery. Monoclonal antibodies in targeted delivery	3
	• Drug targeting : organ specific strategies: By Grietje Molema, D. K. F. Meijer 2001 • Targeted drug delivery Kenneth L. Audus, R. L. Juliano Springer-Verlag, 1991 • Drug targeting: strategies, principles, and applications By G. E. Francis, Cristina Delgado Humana Press 2000 • Brain drug targeting: the future of brain drug development By William M. Pardridge Cembridge university press 2001 • Biomedical aspects of drug targeting By Vladimir Muzykantov, V. P. Torchilin kluwer Academic publishers 2002 • Allosteric receptor modulation in drug targeting N. G. Bowery • Targeting of drugs 6: strategies for stealth therapeutic systems By Gregory Gregoriadis, Brenda McCormack, North Atlantic Treaty Organization. Scientific Affairs Division • Enhancement in Drug Delivery Elka Touitou, Brian W. Barry CRC Press, 2006 • Tumor targeting in cancer therapy By Michel Pagé Humana Press 2002 • Advances in targeted cancer therapyBy Richard M. Schultz Birjhauser Verlag 2005 Immunotherapy for infectious diseases By Jeffrey M. Jacobson Humana Press 2002 • Pharmaceutical Perspectives of Cancer Therapeutics By Ram I. Mahato, Yi Lu Springer Science + Business Media 2009.	

	• Therapeutic Monoclonal Antibodies: From Bench to Clinic By Zhiqiang An Johan Wiley and Sons 2009. • Development of Methods for Carrier-Mediated Targeted Delivery of Antiviral Compounds Using Monoclonal Antibodies Marcia I Dawson, Robert W Sidwell, Bill B Barnett, SRI INTERNATIONAL MENLO PARK CA.	
10	**Elective-III (50 marks) 3hr./week**	
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11	**Elective-IV (50 marks) 3hr./week**	
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12	**PHP 2501– Critical Review of One Research Publication (50 marks) 3hr./week**	
13	**PHP 2502– Seminar (50 marks) 3hr./week**	
14	**PHP 2503– Literature Review of the proposed research topic (50 marks) 3hr./week**	
Elective Subjects		
15	**PHT 2001 – Biopharmaceuticcs and Pharmacokinetics (50 marks) 3hr./week**	
	Biopharmaceutics	
	1. Introduction: Recap of ADME, bioavailability, bioequivalence and factors affecting the same	**1**
	2. Molecular basis of drug Absorption & transport ▪ The Molecular structure and nature of the cell membranes & nuclear membranes ▪ Transcellular absorption 1. Nature of passive transcellular absorption 2. Carriers for the active transport of drugs (With special emphasis on p-glycoprotein & design of pgp inhibitors) 3. Methods of studying the carrier mediated transport ▪ Paracellular absorption 1. The molecular organization of the paracellular space 2. The regulation of paracellular permeability 3. Methods of studying the paracellular absorption ▪ Penetration enhancers & study of their molecular mechanisms of action ▪ Drug delivery to cell organelles 1. Extracellular barriers	**9**

	2. Intracellular barriers Study of cell penetrating peptides and fusogenic peptides and their applications in drug delivery	
	3. Drug Membrane interactions ▪ Possible effects of drugs on the membranes & effect of membrane on drugs ▪ Role of drug membrane interaction in pharmacokinetics & pharmacodynamics of drugs ▪ Development of predictive models for drug membrane interactions (in vitro & computational) ▪ Study of the drug membrane interactions	**3**
	4. Pharmacogenomics ▪ Genetic basis of variation of pharmacokinetics ▪ Methods for pharmacogenomic profiling & study	**2**
	Pharmacokinetic	
	Introduction to ADME and basic pharmacokinetic parameters like Volume of distribution, Elimination half life, Elimination rate constant, Clearance, Area under curve, Bioavailability, calculation of parameters from plasma and urine data	**2**
	Role of Pharmacokinetics in drug discovery; drug development and process development;	
	Mathematical approach to pharmacokinetic modeling; one-compartment open models and data analysis; multiple-dose pharmacokinetics; two-compartment open models; physiological pharmacokinetic models; nonlinear pharmacokinetics; metabolite pharmacokinetics; pharmacokinetic-pharmacodynamic modeling, Case studies and problem solving w.r.t. above including design of controlled release dosage forms and other novel drug delivery systems based on pharmacodynamic and pharmacokinetic rationale.	**9**
	In-vitro-In-vivo correlation	**2**
	Individualization of dosage regimen, conversion from IV dosing to oral dosing, determination of dose, frequency of administration and route of administration, therapeutic drug monitoring, dosing of drug in infants and elders, variability in clinical response and pharmacokinetics w.r.t. renal and hepatic diseases.	**2**
16	**PHT 2002– Intellectual property Rights and Patent Filing (50 marks) 3hr./week**	
	1. Introduction to IP 2. Copyright, Related Rights, Trademarks, Geographical Indications, Industrial Design 3. Patents 4. WIPO Treaties	2 5 15 2

	5. Unfair Competition 6. Protection of New Varieties of Plants 7. Summary and Discussion on IP Rights	2 2 2
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17	**PHT 2003 – Advanced Biochemistry (50 marks) 3hr./week**	
	Proteins: Structures – primary, secondary, tertiary, motifs, structural and functional domains, protein families and macromolecular assemblies.	4
	Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands, Ca^{+2} and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage	4
	Purification and characterization of proteins: Electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes and MS, X-ray crystallography, NMR and Homology modeling, amino acid analysis, cleavage of peptides, protein sequencing.	4
	Protein biosynthesis:Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences.	4
	DNA and nucleic acids:DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms.	6
	Carbohydrates: Mono, di and polysaccharides and their nomenclature, stereochemistry, linkages, conjugates of carbohydrates with other molecules - glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles.	4
	Lipids: Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids	4
	• Lehninger Principles of Biochemistry, Lehninger and Nelson D. L.; Biochemistry, Stryer L.; Molecular Cell Biology, Lodish H. and Darneu J.	
18	**PHT 2004– Drug Metabolism (50 marks) 3hr./week**	
	Introduction to the different pathways of drug metabolism: Phase I and II reactions, sites of drug metabolism, subcellular localization of drug metabolizing enzymes, cofactors required for catalytic reactions	7
	Cytochrome P450 oxidative system: Catalytic cycle of P450 reactions, mechanism of P450 hydroxylation reactions, introduction to CYP450 superfamily of enzymes and their classification, human CYP450s involved in drug metabolism and their typical substrates, inhibitors and inducers.	7
	Introduction to other drug metabolism enzyme isoforms/families Glucuronosyltransferases, glutathione transferases, sulfotransferases, N-acetyltransferases, FMO's.	10
	Methods for studying drug metabolism: Isolated enzymes, recombinant enzymes, subcellular fractions, hepatocytes, perfused liver, in-vivo drug metabolism studies – introduction to these methods, their utility, advantages and limitations	4

	Introduction to in-silico methods for predicting drug metabolism: Principles behind development of these systems, their potential and their limitations.	2
	• Foye's Principles of Medicinal Chemistry, William D.A and Lemke T.L., 5th Edition; Handbook of Drug Metabolism, Woolf T.F.; • Drug Metabolising Enzymes, Lee J.S., Obach S.R., Fisher M.B.; Cassaret • Doull's Toxicilogy, The Basic Science of Poisons, Klaasen C. D., Amdur M.O., and Adull J.; • Fundamentals of Drug Metabolism and Disposition, La Du B.N., Mandel H.L., & Way L.E.	
19	**PHT 2005 – Molecular Biology (50 marks) 3hr./week**	
	Introduction to recombinant DNA technology: Introduction to DNA and its functions, Replication of DNA and its transcription and translation, restriction enzymes and their properties, vectors for use in rDNA technology, creation and introduction of rDNA molecules, cloning and expression of rDNA molecules, cloning and expression systems, their advantages and limitations, application of rDNA technology in production of pharmaceutical and in drug discovery and development.	14
	High throughput screening: Introduction to the principles of screening and the philosophy of HTS, considerations in HTS method development, validation of HTS methodology, some examples of typical HTS assays and the principles involved therein.	4
	Genomics/Proteomics: Introduction to the definitions of various 'omics', introduction to the general field of genomics and proteomics, introduction to some methods used in analyzing gene expression at the mRNA and protein level, basic principles of DNA/Protein microarrays and their applications.	6
	Human Genome Initiative:Introduction to the genome, genome complexity and genome organization, basic approaches towards sequencing of genomes, the approach for sequencing the human genome, sources for obtaining human genome sequence information, data mining of the human genome sequence for information and other potential applications, introduction to bioinformatics.	6
	• Molecular Biotechnology, Principles and Applications of recombinant DNA, Glick B. R. & Pasternak J.J.; Principles of Genome Analysis & Genomics, Primrose S.B. & Twyman R.M.; Gene Biotechnology , Jogdand S.N.; Biotechnology-Theory & Techniques, Gen Engg, Mutagenesis, Separation Technology, Chirirjian J G; Pharmaceutical Biotechnology – A introduction for Pharmacists & Pharmaceutical Scientists, Crommelin D.A. & Sindelar R. D.	
20	**PHT 2006 – Clinical Pharmacy (50 marks) 3hr./week**	
	Introduction to clinical Pharmacy - Scope, objectives and Goal in Health Care - Practice of Clinical Pharmacy in Hospitals and Community	2
	Understanding the Patient - Pharmacist-Patient Interview - Interview Techniques, communication skills	2

	- Medication History, Habits related to the use of OTC medications, foods, allergies and sensitivities - Case Presentation	
	Fundamentals of Diseases - Symptoms and Disease Identification – General Discussion - General and systemic effects of disease - Cardiovascular and other systemic effects of disease and injury - Endocrine and metabolic responses to disease and trauma - Nervous system involvement in disease - Ageing and geriatric diseases - Communicable disease prevention	10
	Therapeutic use of medicine - Drug selection and administration. Problems associated with concomitant therapy. Patient sensitivities, allergies. Precautions during use – Diet control. - Reasons for non-compliance – Poor standards of labeling, social isolation, complex therapeutic regimes, Nature of medication, side effects, lack of doctor / pharmacist/ patient rapport, inadequate patient education. - Strategies for improving compliance – Supplementary labeling, Simplification of therapeutic regimen, patient counseling, use of warning cards, patient education – patient package inserts. - Use of Drugs in geriatric paediatric patients and in pregnancy.	5
	Monitoring the patient in Health and illness - Fluid and Electrolyte Imbalance - Cardiopulmonary Dysfunction - Metabolic disorders - Patient follow-up-discharge interview for hospitalized patients. Precautions and directions during use of medications - Pharmacological and Biochemical examinations their significance - Supervisions of therapeutic success, side effects and adverse effects	4
	Drug Information - Introduction to information resource available. Development of drug information and drug information service. Drug literature utilization, selection, evaluation and communication. Physician-Pharmacist- Interactions Pharmacist-Patient-Interactions	4
	Investigational Drugs and Clinical Research Ethical and Legal Considerations in Evaluation of New Therapy Investigational Drugs- Research Design Bioequivalence and clinical trials of Drug substances – Brief Review	3
	• Clinical Pharmacy Practice Ed. Charles W. Blissit Lea & Febiger Publications	

	• Clinical Pharmacy and Hospital Drug Management ed Lawson and Richards • Clinical Pharmacy- Kleijn Elservier Press, Amsterdam • Applied Therapeutics for Clinical Pharmacists – Koda Kimble M. N. Applied therapeutics Inc, San Francisco • Drug Information for the Health Care Provider vol. I USP DI • Advice for the Patient Vol. II, USP DI • Handbook of Pharmacy Healthcare Diseases and Patient Advice Ed. R. J. Harman Pharmaceutical Press, London • Patient care in Community Practices -R. J. Harman Pharmaceutical Press, London	
21	**PHT 2007 – Packing Technology (50 marks) 3hr./week**	
	Its status and scope in Pharmaceutical Industry	1
	Classification of packaging material into primary and secondary packaging, functions of packaging.	2
	Primary Packaging Material: a. Glass containers (ampoules, vails and bottles) metals (tins for consmetic powders, tubes for skin and ophthalmic ointments, Aluminium containers and foils) 9 Fibers board and paperboard for bulk packaging in containers and drums). b. Containers and laminations of the metal containers Films and Foils- including AL, PVC, used ins trip packaging and blister packaging of tablets, cellulosics and cellophone. c. Plastic- polymers and copolymers, electrosetting and thermoforming (Medium and high density polystyrene PET) d. Equipment in primary packaging including strip packing, blister packing powder filling , liq filling, aerosol filling, snap on closures. e. Design and specification for he containers including bottles, thread, their dimensions and others.	5
	a. Secondary Packaging Materials: Folding cartons and set of boxes, Materials of construction, design and specifications-corrugated fiberboard, Packaging inserts- specifications and test methods and quality control. b. Cushioning – Cushioning materials, applications for impact, vibrations, temperature and humidity closures, applicatures fasteners and adhesives- cap threads, cap liners, aluminium bands, shrink brands, stoppers and plugs, tapes, adhesives. c. Shrink Warp Process	6
	Specifications, quality control tests and methods and evaluation of packaging of materials.	10
	Labels and labeling a. Direct printing heat transfer, ordinary labels, adhesives	2

	b. Standards and Quality Control test including dimensions printing and lists such as folding test, gluing, ageing, block vibration and shock for the boxes c. Toxicity and safety of printing inks	
	Sterilization of containers: Different methods of sterilization for containers (primary) including autoclaving, dry heat, gas sterilization, ionizing and non-ionizing radiations	1
	Stability of packaging materials	2
	Law and regulation governing packaging	1
22	**PHT 2008 – Therapeutic Drug Monitoring (50 marks) 3hr./week**	
	Introduction to Therapeutic drug monitoring:- Definition and introduction, Historical background, Indication for Therapeutic drug monitoring, Monitoring plasma drug levels, Clinical application of Therapeutics drug monitoring, Role of Clinical pharmacist in Therapeutic drug monitoring.	2
	A. Techniques:- I) . Physical methods: II) Detailed study of different chromatographic techniques like- High Performance Liquid Chromatography (HPLC), High Performance Thin Layer Chromatography (HPTLC), Gas Chromatography (GC), Counter Current Chromatography (CCC) III) Immunoassays:- IV) Detailed study of following immunoassays:- Radio Immunoassay (RIA), Enzyme Multiplied Immunoassay Technique (EMIT), Fluoroscence 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). B. Critieria for selection of method for Therapeutic Drug Monitoring: I) Physical properties for drug molecule such as chemical structure present, Molecular weight, Pka Values, Melting and Boiling point, Drug Solubility Concentration range of compound. II) 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.	8 5
	Importance of Therapeutics Drug Monitoring with reference to Adverse Drug Reaction and Drug interaction.	1
	Variation of Clinical Laboratory Tests due to drugs:- Test:- Serum creatinine, Blood Urea Nitrogen, Plasma Glucose, Creatine Kinase, Phosphatases, Amylase, Bilirubin, Serum Proteins, Globulin, Complete blood count and Gifferential Blood count.	2

	Therapeutic Drug Monitoring of specific drugs :- Clinical pharmacokinetics, General guidelines, Sample collection, Time of sample collection, Cilnical comments, Clinical monitoring parameters, Usual dosing parameters, Common toxicities, adverse drug reaction and Drug interactions, Clinical interpretation, Technique used for estimation and importance of Therapeutic Drug Monitoring of following drugs:- Digoxin, Valproic Acid, Amikacin, Procainamide, Aspirin, Gentamicin, Phenytoin, Carbamazepine, Lidocaine, Phenobarbitone, Rifampicin, Lithium, Quinidine, Imipramine, Theophyllin	3
	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 heapatotoxic drugs	3
	Bioequivalance and Therapeutic Eequivalance: Definition and concept, terminology involved, Invivo bioequivalacne criteria and issue, Study design for assessment of the bioavailiability and bioquivalnce, statistical criterias, Regulatory requirements, Type of bioequivalence studies, Pharmacodybamic modles for bioequivalence, Fundametals of integrated PH/PD in models and importance of Bioequivalnce.	4
	Clinical case reports and Discussion	2
	• Pharmacotherapy, Dipiro, Appleton and Lange, Norwalk, Connectiut, Second Edi., 1992 • Drug level Monitoring, John Wiley, Sudee and Beeten, 1980 • Clark's Isolation and identification of drugs, Pharmaceutical press London, 1986. • Clinical Chemistry , Riehterich and column, John Wiley, 1981 • Therapeutic Drug Monitoring and Toxicology by liquid chromatography, Steven Hywong, Vol. 32, Marcel Dekker Inc., 1985 • Therapeutic Drug Monitoring, B. Widdop (Edi), Churchill Livingstone, 3 1985 • Therapeutic Drug Monitoring, and Clinical Biochemistry, Mike Hallworth, Nigel, capps, ACB Venture Publications, 1993 • Simkin Handbook of Therapeutic Drug Monitoring, William J. Taylor, J. Daniel Robinson, Simkin Inc., Gainesville, 1991 • Therapeutic Drug Monintiring Clinical Guide, Second Edi., Abbot Laboratories Diagnostic Division, 1994 • Pharmaceutical Bioquivalance, P. G. Welling, Francies L.S. Tse, Shrikant V.	
23	**PHT 2009– Bulk Drug Technology and Process Chemistry (50 marks) 3hr./week**	
	1. Importance of Development of Bulk Drug Technology 2. Import, Export of Bulk drugs 3. Development of Process chemistry	1 1 6

	4. Plant Layout, Plant Design, Utilities, Process Flowsheets, etc 5. Raw Material Consumption and Cost 6. Safety, Pollution Control and Effluent Treatment 7. Good Laboratory and Manufacturing Practices 8. Quality Assurance and Regulatory Affairs	5 2 3 6 6
	• Manufacturing Technology of Drug by Sitting and Sitting • Encyclopedia of Chemical Technology by Kirk-Othmer • Handling of Hazardous Chemicals and Pollution Control	
24	**PHT 2010– Investigational Drug and Clinical Research (50 marks) 3hr./week**	
	Transmembrane movement of drug molecules, drug absorption, distribution, pathways of drug biotransformation and the environmental and genetic factors and drug metabolism studies, Drug-receptor interactions. Evaluation of new chemical entities including natural products and synthetic compounds Current concepts of drug discovery Preclinical development: carcinogenicity, mutagenicity, teratogenicity Drug registration and clinical trials Post marketing surveillance.	
25	**PHT 2011 – Advances in Receptor Pharmacology (50 marks) 3hr./week**	
	Receptor classification Ion Channels: Transmitter gated channels / ligand gated channels. Eg. Nicotinic receptors, GABAa or glutamate receptors G-protein coupled receptor – G-proteins function, β- adrenergic receptors, muscarinic receptors. Cytosolic receptors / Transcriptional regulators e.g. steroid receptors, hormone receptors Second messenger systems	
	• Pharmacology 3rd edition –H. P. Rang and M. M. Dale • Textbook of receptor Pharmacology by John C. Foreman, Torben Johasen • Drug receptors and their effectors edited by Niel J. M. Birdsall • Drug receptors by H. P. Raug	
26	**PHT 2012– Medicinal Natural Products (50 marks) 3hr./week**	
	General biosynthetic pathways in the formation of secondary metabolites Methods of investigation in biogenetic studies. Biosynthesis of phenyl propanoids Isolation, identification, classification, structure determination and important pharmacological activities of flavonoids. Detailed study of rutin including extraction and isolation. Tumour inhibitors from plants.	

	Pesticides of natural origin. Poisonous plants. Plant allergens.	
	• Medicinal Natural Products- A Biosynthetic Approach. Dewick P.M. 2nd edition/2002 John Wiley & Sons Ltd. • Pharmacognosy & Phytochemistry Medicinal Plants. Bruneton J. 2nd edition/1999 Lavoisier Publishing Inc. • Phytochemical Methods- A Guide to modern techniques of Plant analysis. Harborne J.B. 3rd edition/1998 Springer • Natural Products- A Laboratory Guide Ikan R.2nd edition/1994 Academic Press • Pharmacognosy. Tyler V.E. 8th edition/1981 Lea & Febiger • Textbook of Pharmacognosy. Trease & Evans, 15th edition/2002 Harcourt Publishers • Textbook of Pharmacognosy. Wallis 5th edition/1967 J. & A. Churchill Ltd. • Plant Drug Analysis- A Thin Layer Chromatography Atlas Wagner H. 1984 Springer-Verlag • Wealth of India (11 volumes) Publications and Information Directorate, CSIR 1992 • Atlas of Microscopy of Medicinal Plants, Culinary Herbs and Spices Jackson B.P. CBS Publishers • The Merck Index Merck Research Laboratories 13th edition, 2001 Merck & Co., Inc	
27	**PHT 2013 – Advanced Pharmacology (50 marks) 3hr./week**	
	Experimental evaluation of drugs with preliminary principles of clinical evaluation study of models for testing: Analgesics, Antipyretic an Anti- inflammatory Local anaesthetic Tranguillisers and seadatives Diuretic Anticonvulsants Hypoglycemic agents CNS active CVS active Antihistaminics Immunomodulators etc. Use of monoclonal antibodies. Trnasgenic animal models and Knock-out animals.	
	• Drug Discovery and Evaluation by H. Gerhard Vogel • Screening methodology in Pharmacology –II by Turner and Hebborn • Drug discovery The evolution of modern medicines by Walter Sneader • Evaluation of drug activities by Laurence and Bacharach- Vol. I & II • Safety evaluation of drugs and chemicals by W. Eugene Lloyd	

	• Pharmacology 3rd edition –H. P. Rang and M. M. Dale	
28	**PHT 2014 – Chiral Synthesis (50 marks) 3hr./week**	
	Introduction, concept and importance of chirality Resolution of racemic mixtures Stereoselective and stereospecific synthesis Classification of types of reactions involved in chiral sysnthesis for compounds with one and two chiral centers Examples of reactions of the above types; useful in drug synthesis to be covered. Analytical methods in chiral synthesis.	
	• Chirality in Industry Vol –I, II and III , R. A. Sheldon, • Chiral catalysis, Noyori, Asymmetric Catalysis vol I, II & III , Noyori.	
29	**PHT 2015 – Design of Enzyme Inhibitors (50 marks) 3hr./week**	
	Enzyme structure and function Enzyme kinetics Enzyme Inhibitors: Reversible and irreversible. Active sites and docking analysis, enzyme-substrate interaction, X-ray crystal structure and drug design. Protein data bank. Design of HIV – 1 protease inhibitors, Cytochrome P_{450} inhibitors, DHFR inhibitors, Cyclooxygenase inhibitors. Examples of development of NCE as enzyme inhibitor.	
	• Enzyme Inhibition in Drug Discovery and Development Published Online: 23 Feb 2010, Editor(s): Chuang Lu, Albert P. Li, Print ISBN: 9780470281741 Online ISBN: 9780470538951. DOI: 10.1002/9780470538951Copyright © 2010 John Wiley & Sons, Inc. • Enzymes and Their Inhibitors: Drug Development (Enzyme Inhibitors) by H. John Smith, Claire Simons • Burger's Medicinal Chemistry and Drug Discovery. Copyright ©1999-2010 by John Wiley & Sons, Inc. All Rights Reserved. • Textbook of Drug Design and Discovery, Third Edition ~ Editors: Povl Krogsgaard- Larsen, Tommy Liljefors, Ulf Madsen	
30	**PHT 2016– Quality Assurance and Validation (50 marks) 3hr./week**	
	CGMP – Status and regulations, GLP Validation: Process validation for sterile and non-sterile formulations Validation of Pharmaceutical water systems, validation of utilities, validation of environmental control systems, systems validation and quality audits. Documentation	
	• Beotra's Law of Drugs Medicins and Cosmetics K. K. Singh, L. R. Bugga for the Law Book Co. Pvt. Ltd. Allahabad • Modern Pharmaceutics, G. S. Banker, New York, Marcel Dekker 1990 • Fundamentals of Pharmacy, Blome H. E., Philadelphia, Fea and Febiger, 1985 • Pharmaceutical Production Facilities: Design and Applications, G. C. Cole, New York Ellis Horwood 1990	

	• Microbial Quality Assurance in Pharmaceuticals Cosmetics and Toiletries, S. F. Bloomfield, Chichester, Ellis, Horwood, 1998. • Encyclopedia of Pharmaceutical Technology, J. Swarbrick, New York, Marcel Dekker, 1993 • Remington's Pharmaceutical Sciences, A. R. Gennaro Mac Pub. Co. Easton, Pennsylvania 1990 • Indian Pahrmacopoiea, British Pahrmcopoiea, United States Pharmcopoiea. • Good Laboratory Practice Regulations A. F. Hirsch, New York, Marcel Dekker, 1989 • Good Laboratory Practice Regulations Weinberg New York, Marcel Dekker, 1995.	
31	**PHT 2104– Advanced Instrumental techniques for Material Characterization (50 marks) 3hr./week**	
	Principles, configuration of the instruments, specimen preparation, micro-nanostructure and surface characterization, limitations, pharmaceutical applications of : 1. Scanning microscopy: SEM, SEM & X-ray microanalysis, STEM 2. Scanning probe microscopy: AFM, STM 3. Fluorescence and confocal microscopy 4. Chemical imaging techniques: NIR, MRI 5. Advanced thermal analytical techniques 6. Ultrasound spectroscopy 7. Light scattering spectroscopy based techniques	6 6 3 4 4 2 5
	• Scanning Microscopy for Nanotechnology(Techniques and applications), Weile Zhou, Zhong Lin Wang; Nanocharactisation, Augus I. Kirkland and John L. Hutchison; • Scanning Electron Microscopy and X-ray Microanalysis, J. Goldstein; Scannimg Probe Microscopy The Lab on a Tip, E. Meyer, H.J. Hug and R. Bennewitz.	