SHIVAJI UNIVERSITY, KOLHAPUR

B

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2009

STRUCTURE and SYLLABUS

for

Ph.D. COURSE WORK

(PHARMACY)

Under

FACULTY OF ENGINEERING & TECHNOLOGY

Ph.D. (Pharmacy) Paper II Subject List

Select any one subject of the following subject with consent of guide

1. **Advances in Pharmaceutical Sciences (Pharmacological Screening and Assays)**
2. **Advances in Pharmaceutical Sciences (Separation Techniques)**
3. **Advances in Pharmaceutical Sciences (Molecular modelling)**
4. **Advances in Pharmaceutical Sciences (Isolation And Characterization Of Phytoconstituents)**
5. **Advances in Pharmaceutical Sciences (Optimization Technology)**
6. **Advances in Pharmaceutical Sciences (Biopharmaceuticals)**

Paper - II

ADVANCES IN PHARMACEUTICAL SCIENCES

Note: A candidate has to take any one subject with consent of research guide.

ADVANCES IN PHARMACEUTICAL SCIENCES (PHARMACOLOGICAL SCREENING AND ASSAYS)

Teaching Scheme:	**Examination Scheme:**
Theory: 4 hrs/week	Theory Examination: 100 Marks

Unit-1. General principles of screening, correlations between various animal models and human situations, animal ethics and regulations. Specific use of reference drugs and interpretation of screening results. Human equivalent dose calculations, animal equivalent dose calculation.

Unit-2. Pharmacological screening models for therapeutic areas such as hypertension, cerebral ischaemia, pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease and diabetes.

Unit-3. Pharmacological screening models for infectious diseases.

Unit-4. Correlation between in-vitro and in-vivo screens; Special emphasis on cell based assay, biochemical assay, radioligand binding assay, high through put screening, high through put pharmacokinetic analysis.

References:

1. Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.
2. Turner RA, Screening Methods in Pharmacology, Academic Press, London
3. Goldsteine, Principles of Drug Action, John Wiley and Sons, NewYork
4. Crossland J, Lewis's Pharmacology, Churchill Livingstone, Edinburgh
5. Goodman and Gilman: Pharmacological Basis of Therapeutics, Pregamon Press, New York.
6. Bacq ZM, Capek, Fundamentals of Biochemical Pharmacology
7. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
8. Ghosh MN, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta
9. Kulkarni SK, Handbook of Experimental Pharmacology, Vallabh Prakashan, Delhi
10. Seth UK, Dadkar NK, and Kamat UG: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay
11. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
12. Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
13. Sarewitz D, Pielke RA Jr: Prediction in Science and Policy. In *Prediction: Science, Decision Making, and the Future of Nature*. Edited by Sarewitz D, Pielke RA Jr, Byerly R Jr. Island Press; 2000:11-22.
14. LaFollette H, Shanks N: *Brute Science: Dilemmas of animal experimentation*. London and New York: Routledge; 1996.
15. Kaiser J: Gender in the pharmacy: does it matter? Science 2005, 308:1572.

16. Pound P, Ebrahim S, Sandercock P, Bracken MB, Roberts I: Where is the evidence that animal research benefits humans?
17. Hau J: Animal Models. In *Handbook of Laboratory Animal Science Animal Models*. *Volume II*. 2nd edition.
18. Wall RJ, Shani M: Are animal models as good as we think? Theriogenology 2008, 69:2-9.
19. Overmier JB, Carroll ME: Basic Issues in the Use of Animals in Health Research. In *Animal Research and Human Health*. Edited by Carroll ME, Overmier JB. American Psychological Association; 2001:5.
20. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078932.pdf
21. Shanks N, Greek R, Nobis N, Greek J: Animals and Medicine: Do Animal Experiments Predict Human Response?
22. Houdebine LM: Transgenic animal models in biomedical research.
23. Methods Mol Biol 2007, 360:163-202.
24. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078932.pdf

ADVANCES IN PHARMACEUTICAL SCIENCES (SEPARATION TECHNIQUES)

Teaching Scheme: **Examination Scheme:**

Theory: 4 hrs/week Theory Examination: 100 Marks

Unit-1. Chromatography – Principles, retention parameters, stationary phases, separation and purification methods of Column chromatography, HPLC, vacuum liquid chromatography (VLC), Gas chromatography, Ion exchange, ion-pair, ion suppression, molecular Sieve and affinity FPLC. Chiral separation, chiral stationary phases and its application in pharmaceutical industry.

Unit-2. Detectors for HPLC – types, principles of operation, sensitivity, trouble shooting in HPLC, maintenance. HPLC method development for ionic and non-ionic compounds, matrix effect. Sample preparation techniques – Precipitation, Liquid-Liquid extraction, Solid phase extraction, and microfiltration. Column switching and its applications.

Unit-3. Hypanated Techniques: GC-MS, LC-MS, LC-MS-MS, LC-MS_NMR, LC-MS-IR, LC-S-IR-NMR.

Unit-4. TLC, HPTLC, over pressure layer chromatography (OPLC), centrifugal chromatography and Capillary electrophoresis – Theory and principle, retention parameters, classification and comparative account with respect to HPLC.

References:

1. The Quantitative Analysis of Drugs – D.C. Garratt 3rd Edn. CBS Publishers & Distributors, New Delhi (2001).
2. Pharmaceutical Drug Analysis – Ashutosh Kar , Minerva Press, New Delhi (2001).
3. Remington – The Science and Practice of Pharmacy, 21 Edn. Lippincott Williams & Wilkins.
4. Wim Kok : Capillary Electrophoresis : Instrumentation and Operation.
5. LC/MS –A Practical User's Guide by M.Macmaster , John Wily and Sons Inc.
6. Product safety Evaluation HandBook by S.C. Gad, CRC press 1999.
7. Molecular Biomethods Handbook by R. Raphley and J.M. Walker by Humana Press Inc., 1998.
8. Tandem Techniques(Separation Science Series) by R.P. Scott, John Wily and Sons Inc.
9. Separation Techniques in Chemistry and Biochemistry by R. A. Keller.
10. Bioanalytical Separations, Vol. 4 (Handbook of Analytical Separations) ed., J. D. Wilson, Elsevier publications.
11. Modern methods of pharmaceutical analysis, Roger E. Schirmer.

ADVANCES IN PHARMACEUTICAL SCIENCES (MOLECULAR MODELLING)

Teaching Scheme: **Examination Scheme:**

Theory: 4 hrs/week Theory Examination: 100 Marks

Unit-1. Quantum chemistry and Molecular force fields: Single- and multiple electron systems. Ab initio- methods, Hartree-Fock equations, gaussian basis sets. Orbitals, calculation of partial charges, practical program usage. Molecular force fields: Bonds, angles, torsions. Electrostatics and van der Waals forces, parameterisation from experiments or quantum chemistry. Effective pair potentials, hydrogen bonds. Computation of molecular properties and limitations, examples of commonly used force fields. Energy landscapes: Minimizations, algorithms, normal modes, transition states and reaction pathways.

Unit-2. Bioinformatics: Sequence analysis, protein structure, homology modeling, 3D structure prediction from sequence, chemoinformatics and combinatorial databases. Advanced applications: Free energy calculations from simulations, free energy of solvation, chemical reactions, molecular docking, modern drug design with simulations and quantum chemistry. Introduction to Protein folding, Experimental techniques for studying protein folding, Computational methods for studying protein folding.

Unit-3. Introduction to structure and ligand based drug design and Simulation methods: Pharmacophore model, Homology Model Building, Complementary-based docking, Molecular-dynamics and Monte-Carlo based docking, Fragment based methods, Build-up methodology & bridging methodologies with suitable case studies, Molecular dynamics, equilibration, thermodynamical properties from simulations, stochastic dynamics, energy conservation, conformational analysis.

Unit-4. Molecular Interactions and Recognition: Electrostastics, VDW interactions, hydrophobic effect, molecular recognition (binding energy) Inhibitors types: allosteric, transition state, covalent vs non-covalent, selective and competitive.

References:

1. Leach, A. R. Molecular modelling: principles and applications, 2nd ed., ISBN 0-582-38210-6
2. Charifson P.S (1997) “Practical Application of Computer Aided Drug Design” Dekker, New York.
3. Computational drug design A Guide for Computational and Medicinal Chemists by David C. Young, John Wiley & Sons.
4. K.I.Ramachandran, G Deepa and Krishnan Namboori. P.K. Computational Chemistry and Molecular Modeling Principles and Applications 2008 [1] ISBN 978-3-540-77302-3 Springer-Verlag GmbH.
5. http://en.wikipedia.org/wiki/Molecular_modelling

ADVANCES IN PHARMACEUTICAL SCIENCES (ISOLATION AND CHARACTERIZATION OF PHYTOCONSTITUENTS)

Teaching Scheme: **Examination Scheme:**

Theory: 4 hrs/week Theory Examination: 100 Marks

Unit-1. Extraction techniques such as Soxhlet extraction, microwave extraction, supercritical fluid extraction, solid phase extraction. Isolation and estimation of Secondary metabolites- Alkaloids, Glycosides, Tannins, Flavonoids, Polyphenolics, Terpenoids, Steroids, Organic acids and Proteins.

Unit-2. Isolation and estimation of phytopharmaceuticals:

1) Artimesia -Artimicinine
2) Mapia foetida-Camptothicin
3) Bacopa monnieri-Bacosides
4) Curcuma longa-Curcumin
5) Gymnema sylvestre-Gymnemic acid
6) Mucuna pruriuens –L-Dopa
7) Psoralea corylifolia- Psoralin
8) Taxus baccata-Taxol
9) Tinospora cordifolia- Cordifolioside

Unit-3. Structural elucidation of important phytoconstituents belonging to different groups.

1. Alkaloids –Atropine, Morphine.
2. Glycosides –Strophanthidin.
3. Steroids – Cholesterol.
4. Terpenes – Citral.

Unit-4. Overview of various methods used in characterization including UV, IR, Proton NMR, C13NMR, Mass spectroscopy and crystallographic characterization. Spectral characterization of taxol, pinocembrin, curcumin and digoxin.

References

1. Atal, C.K., Kapur, B.M., Cultivation and Utilization of Medicinal and Aromatic Plants, R.R.L. Jammu.
2. Farooqui, A.A., Sreeramu, B.S., Cultivation of Medicinal and Aromatic Plants University press, 2001.
3. Yoganasimhan, S.N., Medicinal Plants of India, 1st Edition, Interlive Publishing Pvt. Ltd.
4. Medicinal and Aromatic Plant abstracts (MAPA) CSIR, New Delhi.
5. Evans, W.C., Trease and Evans Pharmacognosy, W.B. Saunder & co., London.
6. Wallis, T.E., Text Book of Pharmacognosy.
7. Indian Herbal Pharmacopoeia.
8. Kalia, A.N., Textbook of Industrial Pharmacognosy.
9. Mohammad Ali, Pharmacognosy and Phytochemistry.
10. Bruneton Jean, Pharmacognosy and Phytochemistry of Medicinal Plants.
11. Kaufmann, Natural Products from Plants, CRC Press, New York.
12. Butler, M., Poucher's Perfumes, Cosmetics and Soaps.
13. Panda, Herbal Soaps and Detergents.
14. Vimladevi, Text Book of Cosmetics.
15. D'Amelio, Botanicals, A Phytocosmetic Desk reference.

ADVANCES IN PHARMACEUTICAL SCIENCES (OPTIMIZATION TECHNOLOGY)

Teaching Scheme: **Examination Scheme:**

Theory: 4 hrs/week Theory Examination: 100 Marks

Unit-1. Experiments and optimization process: Design of experiments (DOE) and its need. Identifying formulation and process variables. How to design experiments. Fundamentals of optimization process, need, parameters and methods. Understanding of correlation, linear and non linear regression analysis & mathematical models.

Unit-2. Experimental designs: Design of experiments with special reference to small and large number of variables. Formulation optimization a case study using Factorial Design, Box design, Doehiert Hexagon or Uniform Shell design, Mixture design, Simplex Lattice design, Extreme-Vertices design, Evolutionary methods, D-Optimal, grid search . Generating contour plot and response surfaces, understanding.

Unit-3. Artificial Inteligence & Expert system: Knowledge components, knowledge representation schemes, production systems. Expert system tools, Languages, shells, Lisp Machines and PC based expert system tools. Artificial neuron, Hopfield networks, Kohenen self organizing maps, adaptive resonance. Schemes of neuro-control, identification and control of dynamical system, case study.

Unit-4. Optimization of fermentation and extraction processes: Fermentation: Ethyl Alcohol, Antibiotics, Vitamins, Amino-acids and Pharmaceutical solvents-raw materials, process and process validation Extraction of phytoceuticals and optimization of the extraction process.

References:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann. Third edition, Varghese Publishing House.
2. S. Bolton: Pharmaceutical statistical: Marcel Dekker.
3. Modern Pharmaceutics; By Gillbert and S. Banker.
4. Higgins 1.1., Best, DJ & Jones " Biotechnology, Principles & Applications" Blackwell Scientific Publications, Oxford.
5. Stanbary P.F. and Whitaker, A " Principles of Fermentation Technology" Pergamon Press, Oxford.
6. Bickerstaff GF. " Enzymes in Industry and Medicine,New Studies in Biology" Edwin Arnold, London
7. Klir G.J. and Folger T.A, Fuzzy sets, Uncertainty and Information, PHI
8. Simon Hayking, Neural network, ISA, Research Triangle Parke, 1995.

ADVANCES IN PHARMACEUTICAL SCIENCES (BIOPHARMACEUTICALS)

Teaching Scheme: **Examination Scheme:**

Theory: 4 hrs/week Theory Examination: 100 Marks

Unit-1. Pharmacotherapeutics of Biopharmaceuticals: Biopharmaceuticals, Definition and Classification, Vaccines, Monoclonal antibodies, Abzymes, Recombinant Proteins, Biotherapeutic Proteins. Pharmacokinetics and Pharmacodynamics of Biologicals, Absorption, Distribution, Protein Binding, Elimination, Proteolysis, Pharmacokinetics of Oligonucleotides, Immunogenecity and Pharmacogenetic challenge-Pharmacogenomic variations, Controlled and sustained delivery of drugs, Biomaterials for the sustained drug delivery, Liposome mediated drug delivery. Drug delivery methods for therapeutic proteins

Unit-2. Bioprocess Technology and Bioengineering Aspects: Strategies of biopharmaceutical production using microbiological processes and mammalian cell culture, Operating considerations for bioreactors for suspension and immobilized cultures, Aeration, mixing and hydrodynamics in bioreactors, Fed-batch cultivation of mammalian cells for the production of recombinant proteins, Optimization of high cell density perfusion bioreactors, Selection, scale-up, operation and control of bioreactors

Unit-3. Recent technologies in optimizing Quality Policies/Processings: Characterization and Bioanalytical Aspects of Recombinant Proteins as Pharmaceutical Drugs, Blotting Technique, ELISA technique (Electrochemiluminescence (ECL) - Meso Scale Discovery (MSD)), PCR, Gel-Permeation chromatography, Size-Exclusion chromatography, MALDI-TOF analyzers, FACS-calibur, Patent procedures and international protection

Unit-4. Research Advances in Biotherapeutics: Biopharmaceuticals Expressed in Plants, Strategies of biopharmaceutical discovery using molecular methods like proteomics, genomics and metabolomics, Biophysical Approaches to stabilize biopharmaceuticals/protein pharmaceuticals, Lyophilization/freeze drying and Foam drying technologies to improve stability of proteins, protein engineering, Stem Cell therapies impact to synthesize new biopharmaceuticals.

References:

1. Pharmaceutical Biotechnology, Drug Discovery and Clinical Applications - O. Kayser and R.H.Muller., 2004 Wiley-VCH.
2. Biotechnology and Biopharmaceuticals- Rodney J.Y. Ho and Milo Gibaldi., 2003 Wiley-Liss
3. Biopharmaceuticals: Biochemistry and Biotechnology. Gary Walsh. John Wiley and Sons Ltd., 1998, 2nd Edn.
4. Pharmaceutical Biotechnology. Daan J. A. Crommelin, Robert D. Sindelar. Informa Healthcare; 3rd Edn.
5. Bioprocess Engineering: Basic Concepts 2nd Edn Schuler and Kargi, 2002 Prentice Hall.
6. Svensson's course site: http://www.uiowa.edu/~c046138/KINETICS_HOMEPAGE.htm
7. Malcolm Rowland and Thomas N. Tozer, Clinical Pharmacokinetics: Concepts and Applications, 1995 3rd Edn, Williams & Wilkins, Baltimore.

Ph.D. (Pharmacy) Paper III Open Elective Subject List

Select any one subject of the following Electives with consent of guide

1. **Open elective (Polymorphs And Salts In The Pharmaceutical Industry)**
2. **Open elective (Chemotherapy of Parasitic and Microbial Infections)**
3. **Open elective (Synthetic strategies in synthesis of complex organic molecules)**
4. **Open elective (Clinical Research)**
5. **Open elective (Spectral Analysis)**
6. **Open elective (Drug Regulatory affairs)**
7. **Open elective (Quality Assurance & Quality Control)**
8. **Open elective (Process Analytical Technology)**
9. **Open elective (Industrial Pharmacognosy)**

Paper – III

OPEN ELECTIVE

Candidate should select any one subject from the following with the recommendation of the research guide.

OPEN ELECTIVE (POLYMORPHS AND SALTS IN THE PHARMACEUTICAL INDUSTRY)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Introduction and relation to Drug Discovery and Development. Polymorphism, physicochemical properties and bioavailability with appropriate examples.

Unit-2. Salt Selection, Pseudopolymorphs, Hydrates, Solvates, Amorphous Solids.

Unit-3. Analytical Tools for assessment of polymorphism with reference to Process Development and Formulation Development.

Unit-4. Regulatory Concerns, Patent Implications and uncertainties involved in prediction of polymorphism.

References:

1. Borka, L., Pharmeuropa, 1995, **7**(4), 574 (compiles 200 drugs showing polymorphism).
2. Borka, L., Pharmeuropa, 1995, **7**(4), 586 (lists 200 drugs exhibiting polymorphism).
3. Knapman, K., Mod. Drug Discov., 2000, 57.
4. Stahl, H. P., Wermuth, C. G. (Eds.), Handbook of Pharmaceutical Salts: Properties, Selection and Use, Wiley-VCH, Zurich, 2002.
5. Brittain, H. G., Polymorphism in pharmaceutical solids, in Drugs and the Pharmaceutical Sciences, Vol. 95, Marcel Dekker, New York, 1999, Chap. 5.
6. www.ich.org. and www.usfda.gov and www.fda.gov/cder/ob/default.htm.
7. Teva Pharma, Sertraline hydrochloride polymorphs, U.S. patent 6,452,054.
8. Teva Pharma, Clopidogrel hydrogensulfate polymorph, WO 03/051362.
9. Gupta, M. K., Van Wert, A., Bogner, R. H., J. Pharm. Sci., 2003, **92**, 536.
10. Harper, J. K., Grant, D. M., J. Am. Chem. Soc., 2000, **122**, 3708.
11. Lipinski, C. A., Lombardo, F., Dominy, B. W., Feeney, P. J., Adv. Drug Deliv. Rev., 1997, **23**, 3.
12. Beckmann, W., Org. Process Res. Dev., 2000, **4**, 372.
13. Bauer, J., Spanton, S., Henry, R., Quick, J., Dziki, W., Porter, W., Morris, J., Pharm.Res., 2001, **18**, 859.

14. Chemburkar, S. R., Bauer, J., Deming, K., et al., Org. Process Res. Dev., 2000, **4**, 413.
15. Masui, Y., Kituara, Y., Kobayashi, T., Goto, Y., Ando, S., Okuyama, A., Takahashi, H., Org. Process Res. Dev., 2003, **7**, 334.
16. Liebermann, H. A., Lachman, L., Schwartz, J. B., Pharmaceutical Dosage Forms: Tablets, Vol. 1, Marcel Dekker, New York, 1989, p. 39.
17. Amlodipine maleate vs mesylate, "The Pink Sheet", July 14, 2003, p. 22.
18. McGlone, in Physics and Chemistry of the Organic Solid States, Fox, D., Labes, M. M., Weissberger, A. (Eds.), Interscience, New York, 1965, Vol. 2, p. 725.
19. Desiraju, G. R., J. Indian Chem. Soc., 2003, **80**, 151.

OPEN ELECTIVE (CHEMOTHERAPY OF PARASITIC AND MICROBIAL INFECTIONS)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Introduction to parasitic and infectious diseases, life cycle of the parasites causing following infections, immunology of these infectious diseases.

Unit-2. Biology of tuberculosis, amoebiasis, filariasis, leishmaniasis and HIV infection.

Unit-3. Mechanism of action of drugs used in treatment of above infections. Mechanism of drug-resistance in tuberculosis, leishmaniasis and malaria.

Unit-4. Targets for development of treatment of above infections.

References:

1. Infectious disease secrets, By Robert H. Gates
2. Martin C (2006). "Tuberculosis vaccines: past, present and future". Curr Opin Pulm Med 12 (3): 186–91
3. http://en.wikipedia.org/wiki/Tuberculosis; http://en.wikipedia.org/wiki/Amoebiasis; http://en.wikipedia.org/wiki/Filariasis; http://en.wikipedia.org/wiki/Filariasis; http://en.wikipedia.org/wiki/HIV/AIDS.
4. Berger SA, Marr JS. Human Parasitic Diseases Sourcebook. Jones and Bartlett publishers: Sudbury, Massachusetts, 2006.
5. John P. Overington, Bissan Al-Lazikani and Andrew L. Hopkins, doi:10.1038/nrd2199 Nature Reviews Drug Discovery 5, 993-996 (2006)
6. Hardy LW, Malikayil A. Curr Drug Discov. 2003:15.
7. Shailza Singh, Balwant Kumar Malik, Durlabh Kumar Sharma, Molecular drug targets and structure based drug design: A holistic approach.
8. Current Medicinal Chemistry AntiInfective Agents (2003).
9. Burger: Medicinal Chemistry, John Wiley & Sons N.Y.
10. Ariens: Medicinal Chemistry Series
11. Bunerworther Progress in Medicinal Chemistry Series
12. Comprehensive Medicinal Chemistry - Series –I – VI (Academic Press)

OPEN ELECTIVE (SYNTHETIC STRATEGIES IN SYNTHESIS OF COMPLEX ORGANIC MOLECULES)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Retrosynthetic analysis, disconnections and reliability of reactions, synthons: Donor and acceptor, functional group interconversions, one group carbon-heteroatom and carbon-carbon disconnections, chemo- ,region- and stereo-selectivity considerations , natural reactivity and umpolung. 1, 3 and 1, 5- difunctional compounds.

Unit-2. Principles of synthetic planning : Logic-centered molecular synthesis; Dislocation, synthetic tree, synthons, logical imposition of boundary conditions, direct associated approach; structurefunctionality relationships, functionality and unsaturation levels; Polar reactivity analysis; Control elements, consonant and dissonant circuits; Protocol for synthetic design.

Unit-3. General synthetic reaction patterns and strategies: Aliphatic nucleophilic and electrophilic substitutions, aromatic nucleophilic and electrophilic substitutions, addition to carbon-carbon and carbon- heteroatom multiple bonds, elimination, rearrangements,

oxidations and reductions. Chemistry of protecting groups: protection for alcohols, carbonyl groups, carboxylic groups and amino groups.

Unit-4. Chiral synthesis: The chiral pool approach, stereoselective transformation, chiral auxiliary, chiral catalyst, enzymes as chiral catalysts. Asymmetric synthesis of Ibuprofen, levofloxacin and esomeprazole.

References:

1. Synthetic organic chemistry, Vol-1, Francesco Nicotra.
2. Reaction Mechanisms in Organic Synthesis, Rakesh Parashar, John Wiley & Sons, 2009.
3. Principles of Asymmetric Synthesis, R.E. Gawley & J. Aub, Elsevier.
4. Ledinicer: Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
5. Stuart Warren: Organic Synthesis- The Disconnection, approach (John Wiley & Sons)
6. Stuart Warren : Designing Organic Syntheses: A Programmed Introductionto the Synthon Approach
7. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)

OPEN ELECTIVE (CLINICAL RESEARCH)

Teaching Scheme:
Theory: 3 Hrs. per week
Tutorial: 1 Hr. per week

Examination Scheme:
Uni. Exam: 80 marks
Term Work: 20 Marks

Unit-1. Clinical Research – Introduction, History, Present & Future Scenario, Drug Development – Discovery, Screening, Formulation, Preclinical, Various Phases (Phase I to Phase IV) of Clinical Study, Clinical & Product Registration. BA/BE Studies.

Unit-2. Investigational New Drug & New Drug Application. Regulations – Schedule Y, 21CFR part 11, 50, 54, 56, 310, 312, Drug Registration: Introduction, U.S regulation, Japan regulation, U.K regulation, Indian regulation, Ethnic issues in drug Registration. Ethics – Principles & Practices - History, Ethical Principles, Clinical Trial Regulations, Declaration of Helsinki, Ethics Committee, Informed Consent, Investigator's responsibilities, Vulnerable populations.

Unit-3. Study Setup and monitoring – Feasibility assessment, Site selection, Budget proposal. Monitoring Responsibilities: Type of monitoring visits, Site Initiation, Interim Monitoring, Site close out, monitoring activities, Monitoring methods, Problem solving, Writing monitoring reports. Study Design & Planning – Design, Study Protocol, Case Report Form, Quality of Life, Study Plan, Study Flow Chart, Investigator Selection, Clinical Trial Application. Organization – Contracts & Agreements, Liability & Insurance, Financial Disclosure, Clinical Trial Committees, Logistics & Clinical Laboratory.

Unit-4. Study Conduct and reporting – Essential Documents, Subject Recruitment, Randomization & Blinding, Investigational Product Management, Clinical Trial Supplies. Safety Reporting – Adverse Events, Serious Adverse Events, Adverse Drug Reactions, Patient Care in Clinical Research, Pharmacovigilance. Study Report – Interpretation, Report & Retention of data/report.

References

1. Principal and practice of Pharmaceutical Medicine edited by Andrew j Fleteher. Lionel D Edwards, Anthony W Fox. Peter Stonier Published by John Wiley & sons Ltd.
2. Clinical Pharmacotherapeutics- edited by Kamalesh Kholi. Elsevier Publication.
3. Statistical Methods for Clinical Trials, by Mark X Norleans, Marcel and Dekker, Inc, New York, 2001.

OPEN ELECTIVE (SPECTRAL ANALYSIS)

Teaching Scheme:
Theory: 3 Hrs. per week
Tutorial: 1 Hr. per week

Examination Scheme:
Uni. Exam: 80 marks
Term Work: 20 Marks

Unit-1. Ultra violet and visible spectroscopy: Energy levels and selection rules, Woodward-Fieser and Fieser-Kuhn rules; Influence of substituent, ring size and strain on spectral characteristics; Solvent effect; Stereochemical effect; Non-conjugated interactions. Spectral correlation with structure. Spectral interpretations with drug examples.

Unit-2. Infrared spectroscopy (IR): Characteristic regions of the spectrum. Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency. Determination of stereochemistry. Spectral interpretations with drug examples.

Unit-3. Nuclear magnetic resonance spectrometry (NMR): Magnetic nuclei, chemical shift and shielding, relaxation processes, chemical and magnetic non-equivalence, local diamagnetic shielding and magnetic anisotropy, spin-spin splitting, Pascal's triangle, coupling constant, mechanism of coupling, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, diastereomeric protons, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling and double resonance. Spectral interpretations with drug examples.

Unit-4. Mass Spectrometry (MS): Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications. Spectral interpretations with drug examples.

References:

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)
7. Higuchi : Instrumental Methods of Analysis (CBS Publishers)
8. Analytical Chemistry by open learning series
9. R. J. Hamilton - Introduction to High Performance Liquid chromatography, (Chapman and Hall, London)
10. Ewing - Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York).
11. Modern methods of pharmaceutical analysis, Roger E. Schirmer.

OPEN ELECTIVE (DRUG REGULATORY AFFAIRS)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Concept and historical development of pharmaceutical product registration. Effect of GATT and WTO on commerce of pharmaceuticals. Introduction to IPR, Schedules, NDA, ANDA.

Unit-2. Globalization of drug industries, Export – import policy of drug, WHO certification, Batch Processing / Sample Analysis – Documentation & SOPs, 21 CFR Part 11 Compliance. Indian, American and European patent acts.

Unit-3. Introduction to Bioethics, Ethical issues in Clinical studies, ICMR ethical guidelines for biomedical research, Institutional Ethics committee – composition, role & responsibility, IRB, SOPs – Ethics committee.

Unit-4. Schedule Y with appendices, CDSCO, ICMR guidelines, Other Indian Regulatory Authorities: DCGI/DBT/BARC. Introduction, Historical perspective (Nuremberg, Tuskegee, Belmont, Helsinki), ICH, ICH – GCP and its difference with Indian GCP. Requirements for BA / BE studies.

References:

1. Guidance for preparing documents that meets Regulatory Requirements by Janet Gough.
2. FDA Regulatory Affairs by Donglas J Pisano & David Mantus.
3. FDA Guidelines.
4. ICH Guidelines.
5. ICMR ethical guidelines
6. Drugs & Cosmetics Act
7. Handbook for GCP: 2005.

8. http://www.who.int/medicines/
9. Good Laboratory Practice Regulations by Weinberg, Marcel Dekker Inc., NY.
10. Good Laboratory Practice by Sharma P.P., Vandana Publishing, New Delhi.

OPEN ELECTIVE (QUALITY ASSURANCE & QUALITY CONTROL)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Basic concept of Quality Control & Quality Assurance, Total Quality Management,Philosophy of GMP, cGMP, GLP, ISO, Introduction to ICH guidelines. In Process quality controls on various dosage forms-sterile and non sterile, SOPs for various operations. Quality Assurance guidelines for human blood products and large volume parenterals.

Unit-2. Quality Control Laboratory - Responsibilities and laboratory practices, Routine controls on instruments, standard test procedure sampling plans. Quality control documentation and audits of quality control facilities.

Unit-3. Introduction to validation – Equipment validation, Calibration of equipments, Method validation, Personnel & Process validation, Asceptic validation, Validation of water and air handling systems.

Unit-4. Regulatory Audits, Regulatory Affairs and compliance – QA in Bioanalytical Laboratory, Medical diagnostic laboratory and Clinical Departments. Quality assurance in: Queries and Query resolution, fraud and misconduct, auditing and inspection. Development, Submission and storage of Quality assurance reports.

References:

1. A Practical guide to Quality management in Clinical Trial research, Graham D. Ogg,CRC Taylor and Francis.
2. Clinical audit in Phramaceutical Development, Michael R.hamrell, Informa Health Care.
3. Validation and Qualification in Analytical Laboratories, Ludwig Huber, Marcel Dekker series.
4. Quality Assurance in Pharmaceuticals, OPPI Publication.
5. Pharmaceutical Process Validation by Berry IR and Nash RA (Eds.) Marcel Dekker Inc., NY.
6. How to Practice GMPs 2nd Edn. By Sharma P.P., Vandana Publishing, New Delhi.
7. A Guide to Total Quality Management – Kaushik Maitra and Sedhan K. Ghosh

OPEN ELECTIVE (CONTROL PROCESS ANALYTICAL TECHNOLOGY)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Background of PAT, Goals of PAT, PAT Framework and Process Understanding. Principles and Tools of PAT.

Unit-2. Quality by Design: History, Defining Product Design Requirements and Critical Quality Attributes, The Role of Quality Risk Management in QbD, Design Space and Control Strategy, Quality Systems, Product centric quality by design, Quality by design across the product lifespan, Quality Systems, Steps involved, Real Time Quality Control. Benefits of Quality by Design (QbD

Unit-3. Risk Assessment: Introduction , Scope , Principles Of Quality Risk Management, General Quality Risk Management Process , Risk Management Methodology, Integration of Quality Risk Management into Industry And Regulatory Operations, Definitions, Risk Management Methods And Tools, Potential Applications for Quality Risk Management. Trend Analysis.

Unit-4. Impact of PAT on industry organization & process and regulatory aspects of PAT: Potential benefits PAT to industry, Draft PAT Guidance September 2003, Final PAT Guidance September 2004, PAT Team Certification September 2004, PAT Guidance, PAT Team, ASTM Standards, and support infrastructure Guidance on CFR Part 11 ,Compliance Policy Guide 7132c.08, Draft Guidance on “Comparability Protocol”, Draft Guidance on “Quality Systems Approach to Pharmaceutical CGMP Regulations-Sept 2004, ICH Q8, Q9, and proposed Q10.

References:

1. Guidance for Industry: PAT —A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance, September 2004 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070305.pdf
2. Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, September 2006 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070337.pdf
3. Guidance for Industry: Q9 Quality Risk Management, June 2006http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073511.pdf
4. Guidance for Industry: Q8(R2) Pharmaceutical Development Revision 2, November 2009http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073507.pdf
5. Guidance for Industry: Q10 Pharmaceutical Quality System, April 2009http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073517.pdf
6. Guidance for Industry: Process Validation: General Principles and Practices, January 2011http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf
7. Eriksson, L., Johansson, E., Kettaneh-Wold, N. and Wold, S., "Multi- and Megavariate Data Analysis, Principles and Applications." 1st Edition, Umetrics Academy, June 07, 2001, ch 3-4.
8. http://www.fda.gov/cder/OPS/PAT.htm
9. Food and Drug Administration. PAT - A Framework for Innovative, Manufacturing and Quality Assurance, Draft Guidance. Rockville, MD: 2003.
10. Brown, S., presented at InCINC'94 "Has the 'Chemometrics Revolution' ended? Some views on the past, present and future of chemometrics." Department of Chemistry and Biochemistry, University of Delaware 3. Wold, S., presented at InCINC'94 Chemometrics; what do we mean with it, and what do we want from it?" Institute of Chemistry, Umea University, Umea, Sweden.
11. Kirsch, J., Drennen, J., "Determination of film coated tablet parameters by near infrared spectroscopy." Journal of Pharmaceutical and Biomedical Analysis, 13, 1273-1281, 1995

OPEN ELECTIVE (INDUSTRIAL PHARMACOGNOSY)

Teaching Scheme:	Examination Scheme:
Theory: 3 Hrs. per week	Uni. Exam: 80 marks
Tutorial: 1 Hr. per week	Term Work: 20 Marks

Unit-1. Cultivation of commercially important plant drugs, factors affecting quality of plant and animal drugs like Ashwagandha,Glycerrhiza, Dioscorea, Belladonna, Hyoscyamus, Cinchona, Opium, Digitalis, Senna, Plantago, Mentha, Rauwolfia, medicinal yams,Guggul,Gymnema,Insulin.

Unit-2. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Problems and recent trends in pest management, scope of biological control and use of environment friendly pesticides especially plant derived products, Pyrethroids, pheromones and juvenile hormones.

Unit-3. Technology for Commercial Utilization of following aromatic plants and derived products-Lemon grass, Geranium, Basil, Vetier, Patchouli, Celery and Davana ,Valerian.

Unit-4. Herbal cosmetics and their preparation for skin, hair and dental care. Determination of shelf life of raw drugs, powered drugs, extracts, fractions and finished products.

References

1. Atal, C.K., Kapur, B.M., Cultivation and Utilization of Medicinal and Aromatic Plants, R.R.L. Jammu.
2. Farooqui, A.A., Sreeramu, B.S., Cultivation of Medicinal and Aromatic Plants University press, 2001.
3. Yoganasimhan, S.N., Medicinal Plants of India, 1st Edition, Interlive Publishing Pvt. Ltd.
4. Medicinal and Aromatic Plant abstracts (MAPA) CSIR, New Delhi.
5. Evans, W.C., Trease and Evans Pharmacognosy, W.B. Saunder & co., London.
6. Wallis, T.E., Text Book of Pharmacognosy.

7. Indian Herbal Pharmacopoeia.
8. Kalia, A.N., Textbook of Industrial Pharmacognosy.
9. Mohammad Ali, Pharmacognosy and Phytochemistry.
10. Bruneton Jean, Pharmacognosy and Phytochemistry of Medicinal Plants.
11. Kaufmann, Natural Products from Plants, CRC Press, New York.
12. Butler, M., Poucher's Perfumes, Cosmetics and Soaps.
13. Panda, Herbal Soaps and Detergents.
14. Vimladevi, Text Book of Cosmetics.
15. D'Amelio, Botanicals, A Phytocosmetic Desk reference.