PROPOSED ORDINANCE/REGULATION/CURRICULUM FOR M. PHARM. COURSE

w.e.f. 2011-2012 onwards

DEPARTMENT OF PHARMACEUTICAL SCIENCES, GURU JAMBHESHWAR UNIVERSITY, HISAR

DEPARTMENT OF PHARMACEUTICAL SCIENCES GURU JAMBHESHWAR UNIVERSITY OF SCIENCE AND TECHNOLOGY, HISAR

M.PHARM: COURSES OF STUDY AND SCHEME OF EXAMINATION With effect from July 2011 onwards

			Name of the Pro			of Pha	rmacy	
Program Core		F	Program Elective		Program Qualifying Total Cred		Credits	
(PC) 59			(PE) (PQ)					
					00		65	
			Semest	er l				
			Concor			Title	Toack	ning
S.No.	Course No.		Subjects			inte	Teaching Hours/Week	
							Credits	
1	MPL 501		Advanced Pharma	aceutical	Dena	PC	L = 1 = 1 4 = 0 = 8	8.0
I				iceutical	Drug	FC	4-0-0	0.0
			Analysis					
2	MPL		Paper-I (Specializatio	on)		PC	4-0-8	8.0
	551/601/701/	801						
3	MPL 511/		Therapeutic Drug Mo	nitoring		PE	3-0-0	4.0
3	MPL 511/ MPL 512			onitioning/		FE	3-0-0	4.0
4	MPL 512		Drug Design					0
4			Seminar					2
				Total C	Credits:			22
	I							<u> </u>
			Semeste					
1	MPL		Semester Paper-II (Specialization			PC	4-0-8	8.0
1	MPL 552/602/702/3	802				PC	4-0-8	8.0
1		802)		PC PC	4-0-8	8.0
	552/602/702/		Paper-II (Specialization)				
	552/602/702/8 MPL		Paper-II (Specialization) n)				
2	552/602/702/3 MPL 553/603/703/3		Paper-II (Specialization Paper-III (Specialization) n)		PC	4-0-8	8.0
2	552/602/702/3 MPL 553/603/703/3 MPL 513/		Paper-II (Specialization Paper-III (Specialization Sterile Product Technol) n) ogy/		PC	4-0-8	8.0

	Semester III					
1	MPD 900	Major research Project (To be continued	PC	0-0-18	5.0	
		in IV th Semester)				
2		Seminar	PQ	Grade	2.0	
		Total Credits:			7.0	
Semester IV						
1	MPD 900	Major Research Project including viva	PC	0-0-24	12.0	
2		Seminar			2.0	
		Total Credits:			14	

GURU JAMBHESHWAR UNIVERSITY, HISAR ORDINANCE: MASTER OF PHARMACY (M.PHARM.) COURSES

- 1. **Duration of the Course**: The duration of course study shall essentially comprise of four academic semesters. There shall be actual teaching for of 14-16 weeks in Semester I and II excluding admission, preparation and examination days.
- 2. Eligibility: A candidate for being eligible for admission to the Master of Pharmacy (M.Pharm.) course should have passed Bachelor of Pharmacy (B.Pharm.) examination of Guru Jambheshwar University of Science and Technology, Hisar or B.Pharm. Examination of any other University established by Law in India or any other degree course in Pharmacy recognized as equivalent by Guru Jambheshwar University, Hisar. Admission and eligibility will be based as prescribed by the Guru Jambheshwar University of Science and Technology, Hisar, from time to time in the Hand Book of Information (HBI) in each Academic Session.
- 3. **Courses of Study:** The Master of Pharmacy (M.Pharm.) is presently available in **four** major areas of specialization *viz*. Pharmaceutical Chemistry, Pharmaceutics, Pharmacognosy and Pharmacology.
- 4. Course Curriculum: The course curriculum of Master of Pharmacy (M.Pharm.) shall be of four semesters:
 <u>Semester-I</u> : It shall comprise of four papers for all disciplines, i.e. two compulsory papers, one paper from the field of specialization of the candidate and one elective paper, for all disciplines.
 <u>Semester-II</u> : It shall comprise of four papers for all disciplines, i.e. one compulsory paper, two papers from the field of specialization of the candidate and one elective paper, two papers for the field of specialization of the candidate and compulsory paper, two papers from the field of specialization of the candidate and compulsory paper, two papers from the field of specialization of the candidate and compulsory paper, two papers from the field of specialization of the candidate and compulsory paper, two papers from the field of specialization of the candidate and compulsory paper, two papers from the field of specialization of the candidate and compulsory paper.

one elective paper, for all disciplines. A Seminar will be presented by the

candidate on a topic assigned to him/her and evaluated discipline-wise in terms of grades.

Semester-III: The entire semester would be devoted to Research Work assigned to the candidate. The candidate will be assigned a 'Topic of Research' in the concerned area of his/her specialization by approved Supervisor(s). A seminar will be presented by the candidate on respective research topic and evaluated discipline wise in terms of grades.

<u>Semester-IV</u>: <u>He/she</u> would be required to submit the dissertation on the assigned topic and present a seminar on the same regarding his/her progress report of the work done.

The candidate is required to submit a dissertation in triplicate along with a soft copy on CD latest by 31^{st} July, after IVth semester. A final dissertation evaluation based on the seminar on the work done in the semester III and IV will be conducted by external examination.

5. **Attendance:** As per **HBI**.

6. **Examination:**

a) 20 marks in each subject (theory and practical separately) will be reversed for internal assessment. In theory, these marks will be based upon the average of the marks obtained during the two sessional/minor examinations conducted during each semester. In case of practicals, these marks will be based on day to day assessment of practical work, viva voice laboratory record, etc. There will be no separate s sessional/minor practical examination.

b) 10 marks in each subject (theory and practical separately) will be awarded on the basis of attendance of the candidate, behaviour, etc. in each semester.

c) The main external examination in each theory subject shall be of 70 marks. The student shall attempt any five out of eight questions. Each question shall carry equal marks.

d) The minimum number of marks required to pass the examination shall be as under:

i 50% in theory paper (including sessional/minor and internal)

ii 50% in practical (including sessional/minor and internal)

iii 50% in aggregate

e) No reappear or improvement examination in sessional/minor exams shall be allowed whatsoever.

f) Mobile phones, electronic gadgets, etc. shall not be permitted in the class rooms and laboratories. Students found in possession of these will be strictly dealt with and the equipment will be confiscated.

g) During sessional/minor examination or any departmental/university examination mobile phones/electronic gadgets are not permitted. In case anyone is found in possession of the same in the examination hall will be barred from the minor/sessional examinations of that semester.

h) A candidate who completes the Semester I & II Examinations will be required to submit three copies of the dissertation for Semester-III & IV Examinations, on the research topic assigned to him/her, for evaluation to the Controller of Examinations certified by his/her respective Supervisor/Guide and forwarded by the Chairperson, Department of Pharmaceutical Sciences.

6.1. Seminar:

The candidate for M.Pharm. course will have to present a seminar in II, III and IV semester. The topics for the seminar during Second, Third and Fourth semester will be as under:

Second Semester: Seminar in respective discipline. Third Semester: Seminar will be on the introduction of the topic of dissertation. Fourth Semester: Seminar will be on the progress work of dissertation.

The duration of the seminar will be about 30 min. The candidate may present his/her seminar with the help of Audio-Visual Aids.

Seminar will be evaluated by two recognized Post-graduate teachers of the subject of specialization, ordinarily one of whom will be the guide of the student. The two examiners will jointly award grade for the seminar as follows.

Grade 'O' :	80% or more marks.
Grade 'A' :	60% or more but less than 80% marks.
Grade 'B':	50% or more but less than 60% marks.
Grade 'C':	Less than 50% marks.

If the candidate fails to secure at least 'C' grade in the seminar, he/she will have to again give the seminar in the same semester.

At the second time, if the candidate fails to secure minimum 'C' grade in the seminar, he/she will have to give the seminar in the next semester.

The grade secured by the candidate in the seminar will be communicated to the University for showing in the Statement of marks of the concerned semester.

6.2: If a candidate, after attending the course of studies in the Department does not appear or having appeared failed in one or more course(s) of M.Pharm. Semester-I examination, he/she shall be allowed to register provisionally for the subsequent Semester-II course. However, such a candidate is deemed to proceed to semester III and IV, but his/her dissertation will not be submitted till such time the candidate clears both M. Pharm. I and II semester, but not exceeding the time span permitted

6.3 Submission of Dissertation:

A Supervisor/Guide shall be a full-time post graduate teacher in the Department of Pharmaceutical Sciences, Guru Jambheshwar University of Science & Technology, Hisar. However, a co-supervisor/co-guide could be adopted wherever required in consultation/permission of the Chairman.

A candidate who has passed all the theory papers and practicals of Semester I & II Examinations shall submit the dissertation on or before the date notified by the Chairman/Controller of Examinations.

- 6.4 He/she shall submit two typed copies of the dissertation, in bound form, to the Chairman, duly certified by the Supervisor(s), to be sent to the Controller of Examination (COE) for evaluation.
- 6.5 Provided that if a candidate fails to submit his/her dissertation on or before the prescribed date, his/her *viva-voce* examination will be conducted during the subsequent examination that shall not be earlier than three months from the date fixed in the first instance.
- 6.6 Provided that a candidate shall complete all the requirements of the M.Pharm. Degree in a period not exceeding four years from the date of his/her joining the course.
- 6.7 Dissertation in Department of Pharmaceutical Sciences should present critical exposition of the existing knowledge of the subject and embody original investigation carried out by the candidate in an orderly manner. The candidate should lay down in the dissertation clearly the work done by him/her as an original investigation and the source from which he/she has obtained other information contained in the dissertation. The dissertation should demonstrate that the candidate has been duly trained in research work and is capable to take up fruitful research independently.

7. Setting of Papers :

- a) Written papers shall be set by an External paper-setter from a panel of examiners as recommended by the Chairman of the Department/Board of P.G. and Research Studies. The answer-books shall be evaluated by him/her and the awards shall be submitted to the Controller of Examinations confidentially in a sealed cover.
- b) Examination in Dissertation shall be carried out jointly by the Internal and an External examiner on the basis of an oral (*Viva-Voce*) examination at a place and date notified by the Chairman/University.

The External examiner shall be from the panel of examiners as recommended by Chairman of the Department/ Board of P.G. and Research Studies.

A candidate who fails in the dissertation shall be required to resubmit his/her thesis for fresh assessment not earlier than six months and not later than one year from the date of declaration of result.

- 8. **Successful Candidates :** The successful candidates shall be classified/graded on aggregate of all the three semesters, as under :
- (a) <u>First Class with Distinction</u>: 75% marks and above, if a candidate obtains 50% marks individually in each theory paper and 75% of aggregate marks and further completes the full examination in the normal duration of the course as laid down in this Ordinance.
 The dissertation of the candidate must also be adjudged worthy of distinction by

The dissertation of the candidate must also be adjudged worthy of distinction by the Examiners.

(b) **<u>First Class</u>**: 60% and above but less than 75% marks.

(c) <u>Second Class</u> : 50% and above but less than 60% marks.

A candidate, who has passed the final examination of this University and is desirous of improving his/her performance, will be allowed to appear as an exstudent in even/odd semester examinations, as and when held, twice within the period permissible under clause 8.3. Such a candidate in the first instance shall be required to intimate all the paper(s) in which he/she would like to improve his/her performance. He/she will then appear in the respective paper(s) at the concerned semester examination simultaneously as and when held. If he/she does not improve his/her performance then the higher of the two shall be taken into consideration for the purpose of calculation of aggregate marks.

9. In case of any ambiguity the ordinance/ rules of the university shall be applicable.

M. PHARM. SYLLABUS (w.e.f 2011-12 onwards)

COMPULSORY PAPER-I FOR ALL DISCIPLINES (SEMESTER - I)

MPL 501 : Paper-I : Advanced Pharmaceutical Drug Analysis (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:

1. <u>UV-Visible Spectroscopy</u>: 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.

2. <u>Infrared Spectroscopy</u>: 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.

3. <u>Optical Rotatory Dispersion</u>: Fundamental principles of ORD, Cotton-effect curves — their characteristics and interpretation, Octet rule and its applications, circular dichroism.

4. <u>Nuclear Magnetic Resonance Spectroscopy</u>: The NMR-phenomenon *viz*. spinning nucleus, effect of an external field, precessional motion, precessional frequency, energy transition, chemical shift, ³H-NMR (Tritium NMR-spectroscopy), ¹³C-NMR-spectroscopy, 2D-NMR, interpretations of NMR-spectrum, instrumentation, applications in pharmaceutical analysis.

5. <u>Mass Spectrometry</u>: 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.

6. <u>High Performance Liquid Chromatography (HPLC)</u>: 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.

7.<u>Size Exclusion Chromatography</u>: Distribution coefficient, performance, materials, apparatus, applications in pharmaceutical analysis.

8. <u>Electrophoresis</u>: Moving boundary electrophoresis, zone electrophoresis, continuous electrophoresis (preparative), isotadiphoresis, isoelectric focussing.

9. <u>X-Ray Diffraction Methods</u>: Elementary crystallography, X-ray diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffractometer — interpretation of data.

10.<u>Errors in Pharmaceutical Analysis and Statistical Validation</u>: 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.

11. <u>Gas Chromatography (GC)</u>: Theory, Instrumentation- sample injector, columns, detectors, applications.

12. <u>High Performance Thin Layer Chromatography (HPTLC)</u>: Principles, instrumentation and applications.

13. <u>Thermal Analysis:</u> Principles and applications of thermogravimetric analysis (TGA), Differential thermal analysis (DTA), and Differential scanning Calorimetry (DSC).

14. <u>Research Methodology and Literature Sources</u>: Literature Survey, Citation of References, Presentation of Thesis, Abstract, Introduction, Research Envisaged, Experimental, Results, Discussion, Summary and Conclusion, Bibliography.

Practical Advanced Pharmaceutical Drug Analysis

- 1. UV-Visible analysis of certain pure medicinal compounds: Their absorption bands and identification of structures e.g. Analgin, Paracetamol, Sulphamethoxazole, Ibuprofen, Ampicillin, ChloraMPLenicol, etc.
- 2. Simultaneous estimation of two individual drug substances in some marketed combination formulations e.g. Trimethoprim & Sulphamethoxazole, Paracetamol and Ibuprofen, etc.
- 3. Two-dimensional thin layer chromatography of mixture of amino acids, alkaloids, etc.
- 4. Separation by electrophoresis of protein hydrolysates or mixture of amino acids.
- 5. Comparison of two/three different analytical methods for certain pure drugs e.g. Salbutamol, Ephedrine, etc.
- 6. Experiments based on HPLC
- 7. Structure elucidation of some known/unknown compounds.
- 8. FT-IR/NMR/Mass spectroscopy of compounds
- 9. Case studies on Q.C. Laboratory & Analytical Reporting of Raw Materials, Inprocess and finished products.
- 10. Any other relevant exercises based on theoretical aspects.

- 1. High Performance Liquid Chromatography Knox, J.H. (Ed.)
- 2. Techniques in Liquid Chromatography- Simpson, C.F. (Ed.)
- 3. Thin Layer Chromatography: A Laboratory Handbook- Stahl, E and Jork, H.
- 4. Quantitative Thin Layer Chromatography Touchstone, J.C. (Ed.)
- 5. Fourier Transform Infrared Spectroscopy- Griffiths, R.S. and Haseth, J.A.de
- 6. Infrared Absorption Spectroscopy-Nakanishi,K.
- 7. Quantitative Analysis by NMR-Spectroscopy-Kasler.F.
- 8. The Practice of NMR-Spectroscopy-Chamberian, N.F.
- 9. Instrumental Methods of Analysis-Skoog and West
- 10. X-Ray Methods-Clive Whiston

- 11. Spectroscopic Identification of Organic Compounds-Silverstein
- 12. Statistical Methods in Research and Production-Davies, O.L. and Goldsmith, P.L.
- 13. Statistics for Analytical Chemists-Caulcutt, R and Boddy, R.
- 14. Instrumental Methods of Analysis-Willard, H.H., Meritt, L.L. and Dean, J.A.
- 15. Applications of NMR Spectroscopy in Organic Chemistry-Jackman, L.M. and Sternhell, S.
- 16. Theory and Applications of Ultraviolet Spectroscopy-Jaffe, H.H. and Orchin, M.
- 17. High Performance Thin Layer Chromatography-Zlatkins, A and Kieser, R.E.
- 18. Handbook of Instrumental Techniques for Analytical Chemistry-Frank Settle (Ed.)
- 19. Pharmaceutical Drug Analysis-A. Kar

RECOMMENDED READINGS:

Remington Book of Pharmaceutical Sciences.

Pharmaceutical statistics: Sanford Bolton, Charles Bon

Applied Statistics in the Pharmaceutical Industry by Steven P. Millard and Andreas Krause

Basic statistics and pharmaceutical statistical applications by James E. De Muth

Statistics for pharmacists by Alain Li Wan Po, Alain Wan Po Li -

Statistics in the pharmaceutical industry by Charles Ralph Buncher, Jia-Yeong Tsay Pharmaceutical statistics by David S. Jones

Specialization Papers: PHARMACEUTICAL CHEMISTRY

<u>SEMESTER – I</u>

MPL 551 : Paper-I : Pharmaceutical Chemistry-II (4 – 0 – 8) (Advanced Organic Chemistry)

- 1. <u>Chemical Kinetics & Thermodynamics-</u> Kinetic and thermodynamic requirements for reaction, kinetic versus thermodynamic control. Non-kinetic and kinetic methods for determining mechanisms.
- <u>Stereochemistry-</u> Optical isomerism- Plane, centre & axis of symetry, chiral molecules-test and biological importance of chirality. Stereospecific and stereoselective synthesis. Resolution of racemic mixtures. Geometric isomerism- Resulting from double bonds, monocyclic componds, fused ring systems. Conformational isomerism-conformations in cyclic compounds.
- 3. <u>Reactive intermediates</u> structure, generation, stability and reactivity of carbocations, carbanions, carbenes, nitrenes and free radicals.
 - 7. <u>Alkylation -</u> 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.

- 5. <u>Pericyclic reactions-</u> Molecular orbital symmetry, Woodward-Hofmann rules. Electrocyclic (Diels-Alder reaction) and sigmatropic reactions-Cope, Benzidine rearrangements. Cycloaddition
- 6. <u>Rearrangements-</u>
 - a) Carbon to carbon migration- Wagner-Meerwein, Pinacol-pinacolone, Benzilic acid, Favorskii.
 - b) C to N migration -Hoffmann, Curtius, Beckmann, Schmidt, Lossen.
 - c) C to O migration- Bayer-Villiger, hydroperoxides.
- 7. <u>Reduction reactions of carbonyl and other functional groups-</u>Catalytic hydrogenation, reduction by Group III and Group IV hydride donors, dissolving metal reductions, reductive deoxygenation of carbonyl groups.
- 8. <u>Synthon approach-</u> Concept, half-reactions, FGI, analysis of target molecule, synthetic strategies. Application to synthesis of benzocaine, propranolol, haloperidol, salbutamol and other drugs.
- 9. <u>Miscellaneous reactions.</u>
 - a) Electrophilic Aromatic Substitution –Nitration, halogenation, sulphonation, Friedel-Crafts reactions.
 - b) Nucleophilic Aromatic Substitution –via diazonium ions.
 - c) Electrophitic addition to C=C double bond- halogens, halogen halides, water.
 - d) Carboxylic acids- formation from alcohols and aldehydes, interconversions of carboxylic acid derivatives.
 - e) Reagents used in reduction & oxidation.

Practical Pharmaceutical Chemistry-I (Advanced Organic Chemistry Practical)

- 1. Beckmann Rearrangement Preparation of Benzanilide from Benzophenone Benzophenone → Benzophenone-oxime → Benzanilide
- 2. Fisher-Indolization Preparation of 2-Phenyl indole from acetophenone. Acetophenone → Acetophenone phenylhydrazine → 2-phenylindole
- 3. Perkin's Reaction Preparation of dibromocinnamic acid from Benzaldehyde Benzaldehyde → Cinnamic acid → Dibromocinnamic acid
- 4. Fries Rearrangement Preparation of 2,5-Dihydroxy-acetophenone from Hydroquinone

Hydroquinone \rightarrow hydroquinone diacetate \rightarrow 2,5-dihydroxy acetophenone.

- 5. Conversion of *cis*-isomer to *trans*-isomer Preparation of Diethyl fumarate from Maleic acid.
 - Maleic Acid \rightarrow Fumaric Acid \rightarrow Diethyl fumarate
- 6. Free Radical Coupling Preparation of 2,2-Dihydroxy-1,1-binaphthyl from 2naphthol
 - 2-naphthol \rightarrow Oxidised product \rightarrow 2,2-Dihydroxy-1,1-binaphthyl
- 7. Solving problems based on QSAR
- 8. Computer Aided Molecular Modelling

- 1. Advanced Organic Chemistry Reactions, Mechanisms & Structure, Jerry March
- 2. Organic Chemistry Vol I to III, S.P. Mukherji, S.P.Singh and R.S.Kapoor
- 3. Reaction Mechanisms in Organic Chemistry, S.M. Mukherjee and S.P.Singh
- 4. A Guide Book to Mechanisms in Organic Chemistry, Peter Sykes
- 5. Stereochemistry of Carbon Compounds, Eliel
- 6. Structure and Mechanism in Organic Chemistry, C.K.Ingold
- 7. Organic Chemistry Vols I & II, I.L. Finar
- 8. Molecular Reactions and Photochemistry, C.H.Depny and O.L.Chapman
- 9. Physical Organic Chemistry, Jack Hyne
- 10. Vogel's Text Book of Practical Organic Chemistry .
- 11. Practical Organic Chemistry, F.G.Mann and B.C.Saunders
- 12. Combinatorial Chemistry Synthesis and Applications, Stephen R. Wilson and Anthony W. Czarnik
- 13. Remington The Science and Practice of Pharmacy Vol. I & II, A.R. Gennard
- 14. Applications of Absorption Spectroscopy, John R.Dyer
- 15. Organic Chemistry, Morrison & Boyd
- 16. Experimental Methods in Organic Chemistry, Moore and Dalrymple
- 17. Sterochemistry- R.S. Kalsi
- 18. Organic Chemistry-Solomons G. and Fryhle C., Wiley, New York
- 19. Organic Chemistry-Mc Murry J., Books/Cole, Pacific Grove (USA)
- 20. Synthon approach Stuart Warren
- 21. Organic Chemistry- Pine, Hendrickson

22.

SEMESTER - II

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

(4 - 0 - 8)

- 1) <u>Receptors-</u>Types, structures and functions of receptors, signal transduction and Gproteins, theories of drug-receptor interaction, detailed study of adrenergic, cholinergic, histaminergic, dopaminergic and opiate receptors.
- 2) <u>Principles of drug design</u>- search for lead compound, pharmacophore identification, methods for lead optimization –synthetic analogs, case studies of cimetidine and oxamniquine, prodrugs.
- 3) <u>Nitric oxide-</u> interplay of NO & biological systems. NO biosynthesis and cytotoxicity, NO synthetase inhibitors and their therapeutic significance.
- 4) <u>Autocoids-a</u>) Enkephalins & endorphins b) Prostaglandins & other eicosanoids.
- 5) <u>Antiviral agents-</u> DNA & RNA viruses, viral replication, retroviruses, strategies to design anti-HIV drugs, , antiviral drugs.
- 6) <u>Antineoplastic agents-</u>molecular mechanism of cancer, oncogenes, alkylating agents, antimetabolites, antibiotics, natural products.
- 7. <u>Cardiovascular agents-</u>
 - a) Antiarrhythmics –basis of cardiac arrhythmias, classification of drugs used, mechanism of action, molecular features essential for antiarrhythmic activity.

- b) Antianginal agents-Pathophysiology of angina, classification and mode of action of drugs used, vasodilators.
- c) Antihypertensive agents-etiology of hypertension, basis of drug design, agents affecting sympathetic system, agents acting on smooth muscle, ACE inhibitors, diuretics.
- d) Antihyperlipidemic agents- classes of lipoproteins, hyperlipoproteinemia, development of antihyperlipidaemic agents, mode of action.
- 8. <u>Antifertility agents-</u> methods of fertility control, steroidal and nonsteroidal antifertility agents, abortifacients.

Practical Pharmaceutical Chemistry-II (Advanced Medicinal Chemistry Practical)

Note: All the syntheses should be monitored by TLC and products confirmed by spectroscopy.

- 1. Identification of compounds on the basis of spectroscopy- UV, IR, NMR and Mass.
- 2. Quantitative estimation of functional groups.
- 3. Quantitative estimation of Nitrogen in organic compounds.
- 4. Synthesis of organic compounds of medicinal value such as- paracetamol, phenytoin, DEET, cinnamate esters, 8-hydroxy quinoline, quinoxaline etc.
- 5. Resolution of racemic drugs by different methods such as preferential crystallization and column chromatography of diastereomeric salts.

- 1. Medicinal Chemistry A Biochemical Approach, Thomas Nogrady.
- 2. Essentials of Medicinal Chemistry, Andrujus, Korolkovas.
- 3. Medicinal Chemistry, A. Burger Vols. I to V
- 4. Drug Synthesis, Lednicer and Mischler Vols. I to V
- 5. Principles of Medicinal Chemistry, W. O. Foye
- 6. Strategy of Drug Design, Brucell
- 7. Principles of Drug Design, Smith
- 8. Selective Toxicity, T. Albert
- 9. The Organic Chemistry of the Drug Design and Drug Action, Richard B. Silverman
- 10. Drug Design Vol. I to XV, Ariens
- 11. Chemical and Physical Approaches to Rational Drug Design, David B. Weiner & William V. Williamms
- 12. Medicinal Chemistry : Principles & Practice, F.D. King
- 13. Comprehensive Medicinal Chemistry, C. Hansch et. al.
- 14. Theoretical Drug Design Methods, R. Franke
- 15. Modern Approaches to Chemical Reaction Searching, P. Willet
- 16. Organic Photochemistry, J.M. Coxon and B. Halton
- 17. Technique of Organic Chemistry, E. Weisberger

- 18. Organic spectroscopy- W. Kemp
- 19. Vogel's Text Book of Practical Organic Chemistry .

MPL 553 : Paper III: Pharmaceutical Chemistry-III (4 – 0 – 8) (Chemistry of Natural Products)

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

Practical Pharmaceutical Chemistry-III (Chemistry of Natural Products Practical)

- 1. Isolation and characterization of medicinally active constituents e.g.
 - (a) Eugenol from clove
 - (b) Curcumin from Turmeric
 - (c) Hesperidin from Orange Peel
 - (d) Glycyrrhizin from Glycyrrhiza
 - (e) Piperine from Black Pepper
 - (f) Trimyristin and Myristicin from Nutmeg
 - (g) Pectin from Orange Peel
 - (h) Ascorbic acid from Lemon
 - (i) Sennoside from Senna
 - (j) Menthol from Peppermint oil
 - (k) β -sitosterol from edible oils

- (l) Glycosides
- (m)Alkaloids
- (n) Terpenoids from natural sources
- 2. Degradation reactions of natural products and their identification by micro-TLC, qualitative tests and spectroscopic methods viz. Atropine, caffeine, ephedrine and nicotine.
- 3. Paper chromatography, electrophoresis of amino acids derived from plant sources.

RECOMMENDED READINGS:

- 1. Structure Elucidation of Natural Products by Mass Spectroscopy Vol I & II, H. Budzikiewiez, C.Djerassic and D.H. Williams
- Tables of Spectral Data for Structural Determination of Organic Compounds-E. Pretsch, T,Clerc, J. Seibl and W. Simon
- 3. Heterocyclic Chemistry-Albert
- 4. Biogenesis of Natural Compounds Bernfeld
- 5. An Introduction to the Chemistry of Terpenoids and Steroids-Templeton
- 6. Organic Chemistry of secondary Plant Metabolism-Geissman and Crout
- 7. Chemistry of the Alkaloids-Pelletier
- 8. The Chemistry of the Natural Products- Butterworths.
- 9. Pharmacognosy and Pharmacobiotechnology J.E. Robbers, M.K. Speedie and V.E. Tyler.

Specialization : PHARMACEUTICS

<u>SEMESTER – I</u>

MPL 601 : Paper-I : Pharmaceutics–I (4 – 0 – 8) (Product Development)

- 1. <u>Preformulation</u> :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.
- 2. <u>Pilot plant scale up techniques</u> : 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.).
- 3. <u>Production management & documentation</u> : 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.
- 4. <u>Optimization procedures in formulation and processing</u> : Optimization parameters, classical techniques, statistical design and applied optimization methods.

- 5. <u>Packing materials</u> : Selection and evaluation of materials for containers and closures, pharmaceutical specifications, tests and standards for packing components, Tamper evident packages.
- 6. <u>Drug stability</u> : Shelf-life determination, overages, accelerated stability testing, effect of packaging components on stability, factors affecting stability of pharmaceutical products.
- 7. <u>Dosage forms</u>:Theoretical and practical aspects in the manufacture of different dosage forms
 - a) Solid dosage forms-tablets, capsules, microcapsules.
 - b) Liquid dosage forms-suspensions, emulsions-multiphase and microemulsions; solubilization.
 - c) Parenteral dosage forms-small and large volume parenterals.

Practical Pharmaceutics–I (Product Development Practical)

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

- 1. Theory and Practice of Industrial Pharmacy Lachman, L. and Liberman, H.A.
- 2. Pharmaceutical Dosage Forms Tablets, Vols. I, II and III Lachman, L. and Liberman, H.A.
- 3. Modern Pharmaceutics Banker, G.S. and Rhodes
- 4. Physical Pharmacy Martin, A.
- 5. Bentley's Textbook of Pharmaceutics Rawlins, E.A.
- 6. Pharmaceutical Dosage Forms and Drug Delivery Systems Ansel
- 7. The Science and Practice of Pharmacy-Remington
- 8. Pharmaceutical Preformulation Wells, J.J.

- 9. Encyclopaedia of Pharmaceutical Technology
- 10. Pharmaceutical Dosage Forms-Parenteral Medications-Vol.I,II and III-Avis K.E., Lachman L. and Lieberman H.A.
- 11. Pharmaceutical Statistics-Bolton
- 12. Applied Production and Operation Management-Evans J.R.

<u>SEMESTER – II</u>

MPL 602 : Paper-II : Pharmaceutics–II (4 – 0 – 8) (Biopharmaceutics & Pharmacokinetics)

- 1. <u>General Principles:</u> Drug Absorption, Distribution, Metabolism & Excretion. Factors affecting these processes. Concepts of Bioavailability & bioequivalence.
- 2. <u>Review of Compartment Approaches</u>: Terminology, Kinetics of single and multiple dose administration, one and two compartment models, basics of Pharmacokinetics and Chronopharmacokinetics.
- 3. <u>Non-compartmental Pharmacokinetics:</u> 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.

- 4. <u>Non-Linear Pharmacokinetics</u>: Definition, significance and application, determination of non-linearity, computation of non-linear pharmacokinetic parameters (Km & Vm) by Michaelis-Menten kinetics.
- 5. <u>Clinical Pharmacokinetics:</u> 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.
- 6. <u>Pharmacokinetc & Pharmacodynamic Models</u>: basic concepts, applications and limitations with respect to classical compartmental approaches, inter species scaling, integrated PKPD models.
- 7. <u>In Vitro –InVivo Correlations</u>:Drug dissolution, principles and methodology, different methods of *in vitro-in vivo* correlation, their applications and limitations.
- 8. <u>Controlled release dosage forms</u>: Bioavailability and pharmacokinetics of oral, parenteral, ocular, transdermal CRDF and IUDs.
- 9. <u>Computer Applications and Pharmacokinetics</u>: 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 Pharmaceutics–II (Biopharmaceutics and Pharmacokinetics)

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

RECOMMENDED READINGS

- 1. Biopharmaceutics & Clinical Pharmacokinetics Gibaldi, M.
- 2. Biopharmaceutics & Pharmcokinetics Notari, R.E.
- 3. Biopharmaceutics Swarbrick
- 4. Applied Biopharmaceutics & Pharmacokinetics Shargel, L.
- 5. Dissolution Bioavailability & Bioequivalence Abdov, H.M.
- 6. Clinical Pharmacokinetics : Concepts and Applications Rowland, M. and Tozer, T.N.
- 7. Fundamentals of Clinical Pharmacokinetics- Wagner, J.G.

MPL 603 : Paper-III : Pharmaceutics–III (4 – 0 – 8) (Novel Drug Delivery Systems)

- 1. <u>Fundamentals of Novel Drug Delivery:</u> 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.
- 2. <u>Polymers in CR:</u> 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.
- 3. <u>Oral Controlled Drug Delivery Systems</u>: 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.

- 4. <u>Mucosal Drug Delivery System</u>: Mechanism of trasmucosal permeation, mucous membrane model, buccal, nasal, pulmonary, rectal and vaginal Drug Delivery systems, Intra Uterine Devices.
- 5. <u>Ocular Drug Delivery Systems</u>: Fabrication and application of ocuserts.
- 6. <u>Parenteral Drug Delivery systems</u>: Biopharmaceutical considerations. Solutions, suspensions and emulsions. Implantable therapeutic systems, approaches to develop implants.
- 7. <u>Transdermal Drug Delivery Systems</u>: Drug absorption through skin, basic components of TDDS, types and techniques for development and evolution. Iontophoresis, Sonophoresis and electroporation, Drug permeation enhancers.
- 8. <u>Multiple emulsion and Micro emulsion</u>: 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

Micro emulsion- introduction, structure of micro emulsions, solubilisation and formulaton, transport properties and applications.

- 9. <u>Biochemical and Molecular Biology Approaches to CDDS</u>:
 - a) Microparticulate Drug Carriers- structural aspects, preparation, characterisation, evaluation and applications of Liposomes, Nanoparticles, microspheres etc.
 - b) Other vascular systems- general aspects and applications of niosomes, crythrosomes, pharmacosomes, aquasomes and supramolecules.
 - c) Monoclonal antibodies- preparation and applications.
- 10. <u>Absorption of proteins and peptide drugs</u>: 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 Pharmaceutics–III (Novel Drug Delivery Systems Practical)

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

RECOMMENDED READINGS

- 1. Novel Drug Delivery Systems Chien, Y.W.
- 2. Controlled Drug Delivery Systems Robinson, J.R. and Vincent, H.L.
- 3. Treatise on Controlled Drug Delivery Kydoneus, A. (Ed.)
- 4. Targetted Therapeutic Systems Tyle, P and Ram, B.P.
- 5. Controlled Drug Delivery, Vols. I & II Bruck, S.D.
- 6. Microencapsulation Deasy, P.B.
- 7. Transdermal Drug Delivery Kydoneus, A.
- 8. Opthalmic Drug Delivery Systems Mitra, A.K.

Specialization: PHARMACOLOGY

<u>SEMESTER – I</u>

MPL701: Paper-I: Pharmacology-I (4 – 0 – 8) (Advanced Pharmacology)

- 1. <u>Principles of Clinical Pharmacology :</u> Definition, scope, development of clinical pharmacology, drug receptors, mechanism of action, drug biotransformation, drug administration in special situations like geriatrics, pediatrics, pregnancy and lactation.
- 2. <u>Autonomic Pharmacology:</u> Parasympathomimetics, sympathomimetics, Parasympatholytics, sympatholytics, ganglion and neuromuscular blockers.
- 3. <u>Drug Therapy of Cardiovascular Disorders:</u> Hypertension Congestive Heart Failure, Angina, Arrhythmia, Hyperlipidemia.
- 4. <u>Drug Therapy of GIT disorders:</u> Peptic Ulcers, emesis, diarrhoea and constipation
- 5. <u>Antineoplastic agents</u>: Classification, mode of action, therapeutic applications.
- 6. <u>Drug Therapy of Rheumatoid arthritis and gout:</u> Mechanism of inflammation, COX- I and COX-II inhibitors.
- 7. <u>Chemotherapy of Infectious Diseases:</u>

Antibacterial drugs- sulfonamides, quinolones, penicillins, tetracyclines, chloraMPLenicol, cephalosporins, aminoglycosides, antiviral, antifungal and antiprotozoal chemotherapy, drug therapy of helminthiasis, tuberculosis and leprosy, development of drug resistance.

8. <u>Bioassays:</u> Principles, Types, advantages of bioassays.

RECOMMENDED READINGS:

- 1. B.G. Katzung, Basic and Clinical Pharmacology, Lange Medical Publications, 1998.
- 2. Goodman and Gilman's The Pharmacological Basis of Therapeutics- Mc Millan Publishing Co. Inc.
- 3. D.R. Laurence and P.N.Bennett, Clinical Pharmacology, E.L.B.S./ Churchill Livingstone, U.K.
- 4. H.P.Rang and M.M. Dale, Pharmacology, ELBS/Churchill Livingstone.

Practical Pharmacology-I

(Advanced Pharmacology)

- 1) Bioassays of histamine using gunea pig/rat ileum.
- 2) Bioassay of serotonin using rat fundus
- 3) Bioassay of oxytocin using rat uterus.
- 4) Bioassay of acetylcholine using rat/ cock ileum preparation
- 5) Determination of pA2 value.

RECOMMENDED READINGS:

- 1. Fundamentals of Experimental Pharmacology by M.N. Ghosh, Scientific Book Agency, Calcutta
- 2. Pharmacological Experiments in Intact preparations, Edinburgh University, Pharmacology staff, Livingstone.
- 3. Pharmacological Experiments on isolated preparations, Edinburgh University, Pharmacology Staff, Livingstone
- 4. Handbook of Experimental Pharmacology by S.K.Kulkarni, Vallabh Prakashan, Delhi
- 5. Screening Methods in Pharmacology by P.Turner, Vol.I & II, Academic Press, New York & London
- 6. Drug Discovery and Evaluation by H.G. Vogel and W.H. Vogel, Spring Verlag, Berlin Herideleberg.

SEMESTER - II

MPL 702: Paper-II: Pharmacology-II (4 – 0 – 8) (Recent Trends in Pharmacology)

1. Drug Therapy of Alzheimer's disease

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

Practical Pharmacology –II (Recent Trends in Pharmacology)

- 1. Isolated heart preparation using Langendorff Heart Preparation
- 2. Screening of drugs using rota-rod, photoactometer, Cook's pole-climbing apparatus, analgesiometer, convulsiometer, elevated plus maze.

RECOMMENDED READINGS:

- 1) Receptor-based drug design, Paul Left, Marcel Dekker, Inc.
- 2) Psychopharmacology- The Third Generation & Progress- Herbert Y. Meltzer, Laven Press
- 3) Psychopharmacology-I : Part 1 : Preclinical Psychopharmacology, D.G. Grahame-Smith & P.J. Cowen, Elsevier
- 4) Psychopharmacology-2 : Part 2 : Clinical Psychopharmacology, H.Hippins & G.Winokur, Elsvier Science Publishing Co. Inc
- 5) Drug Receptors & their Effectors ; edited by Nigel, J.M. Birdsall, MC Millan Publishers Ltd.
- 6) Receptor Classification : The Integration of Operational, structural and Transductional Information. D.G.Trist, P.P.A. HuMPLery, P.Left; N.P.Shankley-New York Academy of Sciences
- 7) Text Book of Receptor Pharmacology John C. Foreman, Torben Johansen
- 8) Drug Receptors H.P.Rang, University Park Press

MPL703: Paper-III : Pharmacology-III (4 – 0 – 8) (Pharmacological Screening of drugs)

Study of animal models for screening of following categories of drugs:

- 1) Analgesics
- 2) Anti inflammatory
- 3) Local Anesthetics
- 4) Antianxiety
- 5) Antidepressant
- 6) Antipsychotics

- 7) Anticonvulsant
- 8) Anti Parkinsonism
- 9) Antihypertensives
- 10) Antidiabetics
- 11) Anti-fertility
- 12) Nootropics

Practical Pharmacology -III : (Pharmacological Screening of drugs)

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

RECOMMENDED READINGS:

- 1) Screening Methods in Pharmacology by P.Turner, Vol.I & II, Academic Press, New York & London.
- 2) Fundamentals of Experimental Pharmacology by M.N. Ghosh, Scientific Book Agency, Calcutta.
- 3) Handbook of Experimental Pharmacology by S.K.Kulkarni, Vallabh Prakashan, Delhi.

Specialization: PHARMACOGNOSY

<u>SEMESTER – I</u>

MPL 801 : Paper-I : Pharmacognosy-I (Advanced Pharmacognosy)

1. <u>Comparative Phytochemistry:</u>

Principles of Taxonomy, Study, development, significance of chemotaxonomy with special reference to phytoconstituents viz. Alkaloids, glycoside, terpenes, flavonoids, etc.

- <u>Factors affecting plant drug cultivation:</u> Characteristics of soil, exogenous and endogenous factors essential for plant growth. Fertilizers and their management. Pest Management Herbal Pesticides & Insecticides.
 Plant Tissue Culture:
- 3. <u>Plant Tissue Culture:</u>

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 Pharmacognosy-I (Advanced Pharmacognosy Practical)

- 1. Preparation and Sterilization of Nutrient media, plant cell culture, callus culture.
- 2. Preparation of Herbarium
- 3. Identification of Plant constituents with chromatographic techniques viz. Thin Layer, Preparative TLC, Paper, HPLC, Electrophoresis.
- 4. Soil Analysis.

- 1. The Nature and Properties of Soils (Latest Edn.)– Hyle C. Brady, Macmillian Publishing Co. NY.
- 2. Plant Tissue and Cell Culture Vol.II, Street Botanical Monograph, Blackwell Scientific Publications, London
- 3. Applied and Fundamental Aspects of Plant Cell Tissue and Organ Culture, Narosa Publishing House, New Delhi
- 4. Cultivation & Utilization of Medicinal Plants, Eds. C.K. Atal & B.M. Kapur, R.R.L., Jammu, 1982
- 5. Cultivation & Utilization of Aromatic Plants, Eds. C.K. Atal & B.M. Kapur, R.R.L., Jammu, 1982
- 6. Natural Products for Innovative Pest Managwement, Ed. David L. Whitehead & William S. Bowers, Pergamon Press, Oxford, 1983 or Latest)
- 7. Markets for Selected Medicinal Plants and their Derivatives, International Trade Centre, UNCTAD/GATT, Geneva, 1982
- 8. Pharmacognosy by Trease and Evans, 14th Edn, Baillier-Tindall)
- 9. Modern Pharmacognosy, (Vol. I to IV), E. Ramstad
- 10. Plant Tissue Culture Razdan
- 11. Hand Book of Plant Tissue Culture Bhojwani
- 12. High Performance Liquid Chromatography Knox, J.H. (Ed.)
- 13. Thin Layer Chromatography: A Laboratory Handbook- Stahl, E and Jork, H.
- 14. Quantitative Thin Layer Chromatography Touchstone, J.C. (Ed.)
- 15. Spectroscopic Identification of Organic Compounds-Silverstein et. al.
- 16. Instrumental Methods of Analysis-Willard,H.H.,Meritt,L.L. and Dean,J.A.
- 17. High Performance Thin Layer Chromatography-Zlatkins, A and Kieser, R.E.
- 18. Handbook of Instrumental Techniques for Analytical Chemistry-Frank Settle (Ed.)
- 19. Pharmaceutical Drug Analysis-A. Kar
- 20. Plant Tissue Culture and Biotechnological Application. W. Barz, E. Rainhand, M.H. Zerk

- 21. Practical Evaluation of Phytopharmaceuticals Brain and Turnetr, Wright Scientechnica
- 22. Practical Pharmacognosy, C.K. Kokate, Vallabh Prakashan
- 23. Modern Methods of Plant Analysis-Peach and Tracy, Springer Verlag
- 24. Different relevant Pharmacopoeias, current editions.

SEMESTER - II

MPL 802 : Paper-II : Pharmacognosy-II (4 – 0 – 8) (Herbal Drugs Development)

- 1. Herbal sources of food supplements, Bioavailability enhancers, plant bitters & sweeteners
- 2. <u>Herbal Cosmetics</u>:

Identification, collection and chemical nature of the natural products used in: Hair care, dandruff, dyeing Skin care, anti-wrinkles & anti-aging, leucoderma Scabies

- 3. Anticancer Herbal drugs
- 4. 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
- <u>Standardization of Herbal Drugs:</u> Quantitative Pharmacognosy Modern Instrumental Techniques Biological response measurements.

Practical Pharmacognosy-II

(Herbal Drugs Development)

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

- 1. Herbal Drugs Industry- R.D. Choudhry
- 2. Text Book of Pharmacognosy Wallis, CBS Publishers
- 3. Text Book of Pharmacognosy Trease & Evans
- 4. Pharmacopoeial Standards for Ayurvedic drugs, C.C.A.R.I., New Delhi

- 5. Remington The Science and Practice of Pharmacy Vol. I & II, A.R. Gennard
- 6. Ayurvedic Formulary of India
- 7. All Pharmacopoeias relevant, current editions.

MPL 803 : Paper-III: Pharmacognosy-III (4 – 0 – 8) (Characterization of Plant Constituents)

- 1. Methods of investigation of biogenetic pathways
- 2 Basic principles involved in the phytochemical and biological screening of plant drugs in :

Analgesics, anti-inflammatory, cardiotonic, hypoglycemic drugs and plant immodulators

3. Extraction, Isolation and characterization by chemical and spectral means of various active principles having medicinal, industrial and clinical importance from the following categories:

Alkaloids, glycosides, steroids, antibiotics, vitamins, terpenoids, lipids, volatile oils, coumarins and photosensitizing agents

Practical Pharmacognosy-III (Characterization of Plant Constituents Practicals)

1. Extraction, isolation and purification of following phyto-pharmaceuticals

Caffiene, quinine, piperine, Sennoside, Hesperidine, rutin, vasicine, curcumin, atropine. 2.Data interpretation of compounds isolated above, Solubility, melting point, optical rotation, U.V. and I.R.

3. Chromatography by TLC of compound isolated, where standard available.

- 1. New Natural products and plant drugs with pharmacological, Biological or Therapeutical activity. Eds. H. Wagner and Wolf, Springer Weslong, NY.
- 2. Natural products as medicinal agents, ed. J.L. Beal & E.Reinhard, Hippocratos Verlog Stuttgart.
- 3. Pharmacognosy, Ed. W.C. Evans Gopsons Papers Limited, Noida.
- 4. Structure Elucidation of Natural Products by Mass Spectroscopy Vol I & II, H. Budzikiewiez, C.Djerassic and D.H. Williams
- 5. Tables of Spectral Data for Structural Determination of Organic Compounds, E. Pretsch, T,Clerc, J. Seibl and W. Simon

- 6. Heterocyclic Chemistry, Albert
- 7. Biogenesis of natural Compounds, Bernfeld
- 8. An Introduction to the Chemistry of Terpenoids and Steroids, Templeton
- 9. Organic Chemistry of secondary Plant Metabolism, Geissman and Crout
- 10. Chemistry of the Alkaloids, Pelletier
- 11. The Chemistry of the Natural Products, Butterworths.
- 12. Pharmacogonosy and Pharmacobiotechnology : J.E. Robbers, M.K. Speedie and V.E. Tyler.
- 13. Practical evaluation of phytopharmaceuticals, Brain and Turner, Wright-Scientechnica.
- 14. Phytochemical methods, Harborne, J.B., Champman Hall
- 15. Modern Methods of Plant analysis, Peach and Tracey, All Volumes, Springer-Verlag
- 16. Practical Pharmacognosy, C.K. Kokate, Vallabh Prakashan
- 17. Screening Methods in Pharmacology Turner, Academic Press
- 18. Different relevant pharmacopoeias, Current editions
- 19. Isolation and Identification of Drugs, Clark E.C.G, The Pharmaceutical Press, London.
- 20. Vogel's Text Book of Practical Organic Chemistry.
- 21. Practical Organic Chemistry, F.G.Mann and B.C.Saunders
- 22. Applications of Absorption Spectroscopy, John R.Dyer
- 23. Organic Chemistry, Morrison & Boyd
- 24. Experimental Methods in Organic Chemistry, Moore and Dalrymple
- 25. Stereochemistry- R.S. Kalsi.

ELECTIVES FOR M. PHARM COURSE (ALL DISCIPLINES) :

MPL 511.	Therapeutic Drug Monitoring
MPL 512.	Drug Design
MPL 513.	Sterile Product Technology
MPL 514	Quality Assurance

Elective I

MPL 511 THERAPEUTIC DRUG MONITORING (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.
- 2. Importance of Therapeutic Drug Monitoring with reference to Adverse Drug Reactions and Drug interaction.
- <u>Variation of Clinical Laboratory Tests due to drugs :</u> Tests : Serum creatinine, Blood Urea Nitrogen, Plasma Glucose, Creatine Kinase, Phosphatases, Amylase, Bilirubin, Serum Proteins, Globulin, Complete Blood Count and Differential Blood Count.
- 4. <u>Therapeutic Drug Monitoring of specific drugs :</u>

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 1)
- Valproic Acid 6)
- 2) Gentamicin
- 7) Procainamide
- 3) Lidocaine

4)

- 8) Phenytoin
- Lithium 9) Phenobarbitone Ouinidine
- 5) Theophylline 10)
- 5. 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.

RECOMMENDED READINGS:

- Pharmacotherapy Dipiro, Appleton and Lange, Norwalk, Connectciut. 1)
- 2) Drug level Monitoring. John Wiley, Sudee and Beeten.
- Clark's Isolation and identification of drugs. Pharmaceutical Press London. 3)
- Clinical Chemistry Riehterich and column, John Wiley. 4)
- Therapeutic Drug Monitoring and Toxicology By Liquid Chromatography, 5) Steven Hywong, Vol. 32, Marcel Dekker Inc.
- Therapeutic Drug Monitoring B.Widdop (Edi.), Churchill Livingstone, 3. 6)
- Therapeutic Drug Monitoring and Clinical Biochemistry Mike Hallworth, Nigel, 7) Capps, ACB Venture Publications.
- Simkin Handbook of Therapeutic Drug Monitoring William J. Taylor, J.Daniel 8) Robinson, Simkin Inc., Gainesville.
- 9) Therapeutic Drug Monitoring Clinical Guide, Abbott. Laboratories, Diagnostic Division.
- 10) Pharmaceutical Bioequivalence, P.G. Welling, Francis L.S. Tse, Shrikant V.

Elective II

MPL 512 DRUG DESIGN (4 - 0 - 0)

- 1. Introduction: Rationale of drug design, drug-receptor interactions, application of biotechnology for drug discovery. Approaches to drug design, method of variation, biochemical and physiological approaches.
- Lead compound Search & Optimization : Search of lead compound from natural 2. 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.
- 3. 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, Fibonacci Search, Computer Aided Drug Design (CADD).

- 4. <u>Prodrugs</u>: Objectives of Prodrug Design increasing bioavailabilty, inproving membrane permeability, prolonging activity, reducing side effects, removing undesirable properties. Prodrugs from different functional groups-carboxyl, amino, hydroxyl etc.
- 5. <u>Enzyme Inhibitors</u>: Theory of enzyme action and inhibition, types of inhibitionreversible and allosteric inhibition, medicinal importance of enzyme inhibitors – NSAIDs, Sulphonamides, β -lactam antibiotics, ACE inhibitors, carbonic anhydrase inhibitors.
- 6. <u>Recent Advances in :</u>
 - i) Anti-AIDS agents.
 - ii) Antineoplastic agents.
 - iii) Drugs used in Alzheimer's disease.
 - iv) Antimalarials.
 - v) Antibiotics.
- 6. Drugs through microbial transformation.

RECOMMENDED READINGS :

- 1. Comprehensive Medicinal Chemistry, Vol. I to VI C Hansch.
- 2. Principles of Drug Design-W.Smith.
- 3. Drug Design, Vol. I to XV-Ariens.
- 4. Medicinal Chemistry, Vol. I to V Burger A.
- 5. Organic Chemistry of Drug Design and Drug Action Richard B., Silverman.
- 6. Text book of Drug Design and Development P.Krogsgaard.
- 7. Computer Aided Drug Design -T.J.Perum and C.L.Propst.
- 8. Perspectives in Medicinal Chemistry Bernard Testa and Walter Fuhrer.

Elective III :

MPL 513 STERILE PRODUCTS TECNOLOGY (4-0-0)

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

RECOMMENDED READINGS :

1. Pharmaceutical Dosage forms – Parenteral Medications – Vol. I, II and III, Avis K.E, Lachman L. and Lieberman H.A.

- 2. Aseptic Process Validation Carleton and Agallaco.
- 3. Sterile Dosage Forms Turco S. and King R.E.
- 4. Encyclopaedia of Pharmaceutical Technology.

Elective IV

$MPL 514 QUALITY ASSURANCE \qquad (4-0-0)$

- 1. Interpretations of current good manufacturing regulations.
- 2. Auditing function in the Total control of Quality,
- 3. Process validation
- 4. Control of components, containers and closures.
- 5. Production and process controls.
- 6. Packaging and labelling controls.
- 7. Laboratory controls.
- 8. Records and Reports.
- 9. Returned and Salvaged Drug products. Repacking and Re-labelling.
- 10. Problem Analysis and Corrective Action Report.
- 11. Quality control of Biologicals-International Biological Standards.
- 12. Quality Control of Antibiotics.
- 13. Evaluation of Sustained Release Products.

- 1. Process Validation Loftus & Nash.
- 2. Quality Control Cooper Vol. I & II.
- 3. Good Manufacturing Practices for Pharmaceutical Willing S.H., Tuckerman M. and Hitchings W.S.
- 4. SOP Guidelines D.H. Shah, Business Horizons Pharmaceutical Publisher.
- 5. Project Management and Plant Layout, Vol. 86, Marcel Dekker.
- 6. Pharmaceutical Statistics Bolton.