



**STRUCTURE FOR THEORY & PRACTICAL PAPERS
WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR
MASTER DEGREE IN PHARMACEUTICAL TECHNOLOGY (M. PHARMA) IN
PHARMACOLOGY**

SEMESTER-I

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-102(1)	Advanced Pharmacognosy-I	4				3
02	MBS-101	Bio-Statistics (Common paper)	4				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	4				3
04	MPT-102(2)	Biogenesis and Chemistry of Natural Products	3				2
SESSIONAL							
05	MPT-181	Seminar					1
06	MPT-192 MPT-191	Advanced Pharmacognosy-I Lab Pharmaceutical analysis Lab			4 4		3 3
							17

FULL MARKS FOR PAPER WITH 2 / 3 CREDIT POINT = 100

FULL MARKS FOR PAPER WITH 1 CREDIT POINT = 50

FULL MARKS FOR PAPER WITH 5 CREDIT POINT = 200

FULL MARKS FOR PAPER WITH 9 CREDIT POINT = 300

SEMESTER-II

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-202(1)	Advanced Pharmacognosy-II	3				2
02	MPT-209	Pharmaceutical Bio-technology (Common paper)	4				3
03	MPT-212	Process validation & CGMP (Common Paper)	4				3
04	MPT-202(2)	Herbal Drug Development and Standardization	2				2
SESSIONAL							
05	MPT-281	Seminar					1
06	MPT-292	Advanced Pharmacognosy-II Lab			4		2
							13



SEMESTER-III

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-314	Research Methods & Clinical Trials	3				2
02	MPT-391	Synopsis					5
03	MPT-392	Presentation					3
							10

SEMESTER-IV

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-492	Thesis					9
02	MPT-492 (1)	Defence of Thesis					3
							12

The Synopsis and presentation of 1st semester and Thesis and Defence of Thesis in 4th Semester should be assessed in presence of External Examiner(s). The Final Credit should be awarded to the student of the above mentioned subjects by both the internal and external examiners.



M. PHARM. SYLLABUS FOR PHARMACOGNOSY

SEMESTER-I

ADVANCED PHARMACOGNOSY-I

Code: MPT-102(1)
Contact: 4 hr per week
Credits: 3
Full Marks: 100

1. General introduction to the importance of Pharmacognosy in herbal drug industry. General aspects involved in the cultivation of medicinal plants.
Factors involved in production of crude drugs. (i) Exogenous (ii) Endogenous factors (iii) Mineral supplements (iv) Nutrients and (v) Growth regulators and inhibitors. Pest control and study of pesticides with special importance to natural pesticides.
2. Systematic study of medicinal plants cultivated in India with reference to constituents and uses of Senna, Clove, Opium, Ispaghula, Solanum, Lkhasianum, Vinca, Garcinia, Ashwagandha, Lemongrass, Acorus calamus, Safed musli, Turmeric, Pepper, Coffee, Aloe and Henna.
3. Principles of Ayurvedic systems of medicines, their merits and demerits, Introduction to different dosage forms, Preparation Methods of Ayurvedic medicines. Approximate equivalents of doses in Indian and Metric system, English equivalents of Ayurvedic clinical conditions and diseases.
5. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants.
4. Study of information retrieval methods of natural plants and herbal data base. Phytochemical and Pharmacological literature review of *Gymnema sylvestre*, *Azadirahcta indica*, *Adhatoda vasica*, *Asparagus racemosus*, *Commiphora mukul*, *Podophyllum Hexandrug*, *Ocimum sanctum*.

Recommended Books :

1. Cultivation of Medicinal Plants by CK Atal and BM Kapoor.
2. Cultivation and Utilization of aromatic plants by CK Atal and BM Kapoor.
3. Ayurvedic formulary of India, Govt. of India.
4. Homeopathic Pharmacopoeia
5. Unani Medical Systems
6. Bibliography of Pharmacognosy of Medicinal Plants by Mitra Roma, ELBS Edn.
7. Indian medicinal Plants by Kirthikar, Basu.
8. Indian material Medica by K.M. Madkarni.
9. Plant propagation – principle & practices by hertamann Kester.
10. Pharmacopoeial Standards for Ayurvedic formulations – CCRAS, Delhi.
11. Selected topics in Experimental Pharmacology – VK Seth.
12. The use of Pharmacological techniques for the evaluation of natural products by BN Chavan and RC Srimal (CDRI).

BIO-STATISTICS

Code: MBS-101
Contact: 4 hr per week
Credits: 2
Full marks: 100

1. An introduction to statistics and bio-statistics collection and organisation of data: Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.
2. Probability: Definition and probability distributions, normal, binominal and polynomial distributions, continuous data distribution, fiducial limits, pobit and logit analysis.
3. Regression: Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.
4. Parametric tests: Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients.



MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code: MPT-101

Contact: 4 hr per week

Credits: 3

Full marks: 100

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.
2. Infrared spectroscopy
Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR
3. Ultraviolet spectroscopy:
Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore $s \rightarrow s^*$, $h \rightarrow s^*$, $p \rightarrow p^*$, $h \rightarrow p^*$, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications
4. Nuclear Magnetic Resonance spectroscopy:
A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.
B. ^{13}C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.
5. Mass Spectrometry:
Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.
6. Thermal analysis:
Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.
7. Pharmacological evaluation of drugs in biological fluids: Bioassay.
8. Microbiological assays.
9. Radioimmunoassays.
10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

BIOGENESIS & CHEMISTRY OF NATURAL PRODUCTS

Code: MPT-102(2)

Contact: 3 hr per week

Credits: 2

Full Marks: 100

1. Methods of investigation of biosynthetic pathways, tracer techniques and autoradiography.
2. Drug Constituents and their biosynthesis:
Alkaloids: Ephedrine, Hyoscyamine, Quinine, Morphine, Ergometrine, Reserpine, Vincristine.
Glycosides: Digitoxin, Scillaren, Glycyrrhizin.
Steroids: Sitosterols, Hecogenin, Diosgenin.
Coumarin: Umbelliferone.
Flavones: Hesperidin, Myrecetin.
3. Terpenoids: Source and structure elucidation of camphor, eugenol, Taxol and artemisinin.
4. Carotenoids: Source and structure elucidation of Lycopene, Vitamin A, β -Carotene, and Bixin.



5. Polypeptides and Proteins: General methods of separation, general methods of degradation and end group analysis, general methods of synthesis of peptides. Sequence analysis, secondary and tertiary structure of proteins; chemistry of Insulin.

RECOMMENDED BOOKS:

1. Jean Bruneton, Pharmacognosy and Phytochemistry of medicinal plants Techniques and Documentation, Lavoiser, 1995.
2. Wickery, M.L., Secondary Plant Metabolism, MC Millan Press, London.
3. Introduction to Alkaloids, A Biogenic Approach, Willy, New York.
4. Vinod D. Rangari, Pharmacognosy and Phytochemistry, Career publication, Nashik.
5. Tyler, E., Brady, R., Pharmacognosy, Philadelphia P.A., U.S.A.
6. Kaufmann, Natural Products from Plants, CRS Press, New York.
7. Nakanishi K., Chemistry of Natural Products, Kodausha Book Publishing Company, Osaka (Japan).
8. Swain, T., Chemical Plant Taxonomy, Academic Press, London.
9. Harborne, J.B., Phytochemical Methods, Chaparan & Hall, London.

ADVANCED PHARMACOGNOSY-I PRACTICAL

Code: MPT-192
Contact: 4 hr per week
Credits:3
Full Marks: 100

1. Macroscopical and microscopical evaluation including Quantitative microscopy.
2. Physical, Chemical and Biological evaluation in quality control of crude drugs.
3. Estimation of plant phytoconstituents using modern methods like HPTLC.
4. Extraction and isolation of volatile oils.
5. UV and IR analysis of the following isolated phytochemicals and determination of their purity.
 - a) Caffeine.
 - b) Piperine.
 - c) Quinine.
 - d) Andrographolide.
 - e) Curcumin.
6. Study on the Micro wave assisted extraction technique of plant drugs.

PHARMACEUTICAL ANALYSIS PRACTICAL

Code: MPT-191
Contact: 4 hr per week
Credits:3
Full Marks: 100

1. Practical based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.
Microbial analysis of Vitamins and Antibiotics.
Pharmacological Bioassay of some drugs.



SEMESTER-II

ADVANCED PHARMACOGNOSY II

Code: MPT-202(1)
Contact: 3 hr per week
Credits: 2
Full Marks: 100

1. General methods and Principles of extraction methods, types of extraction and their merits and demerits. Selection and purification of solvents for extraction, methods of isolation, purification and identification of photoconstituents.
2. Chromatography: General Principles and Applications of Adsorption, Ion-exchange, Molecular-sieve, Affinity, Hydrophobic and Chiral chromatography, Detailed study of TLC, Column chromatography and high pressure thin layer chromatography, HPLC and GLC.
3. Plant tissue culture techniques & its application in relation to phytopharmaceuticals: Techniques of initiation & maintenance of various types of cultures, Immobilized cell techniques (survey of recent advances), Germ plasm storage, biotransformation studies, recent advances in elicitor techniques and production of biological active constituents in static, suspension, multiple shoot cultures. Bioreactors for production of biologically active constituents and other applications of plant tissue culture techniques. Biosynthetic potential of tissue cultures and factors affecting production of secondary metabolites by tissue culture techniques.
4. Comparative Phytochemistry, its history, concepts, applications and methods, DNA finger printing.

RECOMMENDED BOOKS:

1. Pharmacognosy by G. E. Trease, W. C. Evans, ELBS.
2. Pharmacognosy by Varro E. Tyler, Lynn R. Brady, James E. Robbera.
3. Plant Physiology by Frank B. Salisbury, Cleon W. Rose, CBS Pub. Delhi.
4. Antibiotics Isolation & Separation by M. L. Wenisten, G. H. Wagman.
5. Introduction to Biotechnology by Bullock, John.
6. Biotechnology of Higher plants by Gordon E. Russel
7. Modern Biotechnology by S. B. Primrose.
8. Plant cell culture – A practical approach by R. A. Dixon.
9. Plant cell culture technology by M. M. Yeoman.
10. Plant tissue culture by Dennis N. Butcher, David. S. Ingram.
11. Plant tissue culture by Pitman.
12. Plant tissue culture – theory & practice by S. S. Bhajwani, M. K. Razdan.
13. A Laboratory guide to Organic Natural Products by R. Ikan
14. Environmental Chemistry by Anil Kupur. D.
15. Basic gas chromatography by Menair, Bondhi.
16. Quantitative thin layer chromatography & its industrial application by Trieber. L. R.
17. Biotechnology of Industrial antibiotics by E. J. Vardamme.
18. Chromatography of alkaloids by Verpoorte Swendson.
19. Elements of chromatography by P. K. Lala.
20. Introduction to chromatography – theory & practice by V. K. Srivastava, K. Kishore.
21. Principles of Biotechnology by Leininger.
22. Handbook of Vitamins by L. S. Machlein.
23. Industrial Microbiology by L. E. Cassida.
24. Microbial Technology by Pepler, Perlman.
25. Burger's Medicinal Chemistry by M. I. Wolff.
26. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry by Deorge. R. F.
27. Phytochemical methods of chemical analysis by Harbone.
28. Cytogenetics and evolution of plant Breedings by R. S. Shukla.
29. Introduction to organic laboratory techniques by Pavia Lampman.
30. Drug analysis by chromatography by Egon stahl0.
31. Secondary plant metabolism by Margaret L. Vikery, Brian Vikery.
32. Practical Pharmacognosy by Dr. C. K. Kokate.
33. Practical Pharmacognosy by Dr. P. K. Lala.



34. The review of Natural products – Ara Dermarderosia.
35. Phytochemical Dictionary – Jestorey. B.Harbone.FRS.
36. PDR for Herbal medicines.
37. Methods in plant tissue culture – U.Kumar.
38. Plant cell and tissue culture – Angela Stafford and Grahamwarren.
39. Phytochemicals – R.Bidlack, Tomaye, s.Meskin.
40. Propagating plants – Alan toogood.
41. Modern methods of plant analysis –High performance Liquid chromatography in Plant science –H.F.Linskens and J.F.Jacksons.

PHARMACEUTICAL BIO-TECHNOLOGY

Code: MPT-209

Contact: 4 hr per week

Credits: 3

Full marks: 100

1. Systems and methods of molecular biology: Introduction to genetic engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells, use of mutants, genetic analysis of mutants, genetic recombination, complementation.
2. Gene cloning: Nucleic acid isolation cloning vectors (some examples), enzymes used in molecular cloning, cloning methods (some examples)
3. Gene expression: Gene expression, some examples in E. coli in baculovirus in mammalian cells.
4. Fermentation technology: Design, operation and characteristics of fermentation processes, cell growth and production regulation, product biosynthesis and accumulation, instrumentation and bio-process control.
5. Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach, future directions.
6. Antibiotic biosynthesis genes and their use in developing new antibiotic from micro organisms. Methods for isolating new antibiotics, genetic systems and molecular tools for analysis of antibiotic, bio-synthesis, cloning and analysis of antibiotic biosynthesis genes, genetically engineered hybrid antibiotics.
7. Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential, methods of protein drug delivery future perspective.
8. Prospects in gene therapy, Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations.
9. Biotechnology in pharmaceutical industry: Major areas for biotechnology in the pharmaceutical industry such as antibiotics, sexual re-combination, recombinant DNA technology, monoclonal antibody, regulatory proteins (human insulin, interferon, therapeutic peptides) commercial aspects, priorities for future biotechnological research.
10. Sterilization and sterility testing: principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.

RECOMMENDED BOOKS:

1. J.D.Watson, "Molecular Biology of the cell".
2. J.D.Watson and Tooze, "Recombinant DNA techniques": A short course.
3. Benjamin Levin, "Genes V".
4. Pepler, "Microbial Technology" I & II.
5. Old & Primrose, "Genetic Manipulations"
6. I.P. 1996, Vol.-I & II

PROCESS VALIDATION AND CGMP

Code: MPT-212

Contact: 4 hr per week

Credits: 3

Full marks: 100

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc.
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development.
3. Development of new analytical method and its validation.



4. In-process quality control tests for various dosage forms including packaging and labeling operations.
5. Brief introduction to general requirements of health regulatory agencies such as US FDA, WHO etc. Preparation of documents for new drug application and export registration.
6. History and various phases of drug development and drug approval, Investigational New drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA), Content, development flow sheet and format, exclusivity, concept of paragraph I to IV, Clinical study and basic concepts of Good clinical practice.
7. Concepts in validation, validation of manufacturing and analytical equipment. Process validation in production of pharmaceuticals. Electronic records (21CFR11)
8. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER.

RECOMMENDED BOOKS:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

HERBAL DRUG DEVELOPMENT AND STANDARDIZATION

Code: MPT-202(2)
Contact: 2 hr per week
Credits: 2
Full Marks: 100

1. Herbal based Industry: Scope, study of infrastructure, staff requirement, project profiles, plant and equipment, processing, research and development, regulatory requirement. Pilot scale up techniques.
2. a) Industrial methods and preparation of standardized extracts, principle, methods, merits and demerits. Preparations of standardized extracts of Garcinea, Forskolin, Garlic, Turmeric and Capsicum.
b) Preparation and Standardizations of herbal formulation : Shapoo's syrups, Chyanvanprash, powders, Pintments, face packs, tablets and capsules.
3. Nutraceuticals: Scope, herbal sources of food supplements, taste enhancers, colours, volatile oils of commercial significance, perfume industries.
Standardization of Ayurvedic and Homeopathic medicines. Problems in Standardization of these Products, WHO Guide lines.
4. Bio-statistics and design of experiments: Regression, tests of significance, F-test and analysis of variance : 1-way, 2-way classification, chi-square test.
5. Principles of randomization, replication and local control, completely randomized block of the above designs in pharmaceutical research. Bio assay-different types: dose effect relationships, calculation of LD50, ED50, probit analysis. Statistical quality control, process control, control charts, acceptance sampling – sampling plans.
6. Screening of natural products for the following biological activities – analgesics, anti-inflammatory, antidiabetic, diuretic, antifertility, antiepileptic, antihypertensive and antiarrhythmic activities.

Recommended Books:

1. Vogel HG and Vogel WH, Drug discovery and evaluaion, pharmacological assays, springer – verlag.
2. Ayurvedic Pharmacopoeia
3. Thin layer chromatography by E. Stahi
4. Herbal Phamacopoeia
5. Herbal drugs industry by R.D. Chaudari.
6. SC Gupta and VK Kapoor, Fundamentals to applied statistics
7. Alvin E. Lewis, Bio statistics.
8. Wealth of India CSIR, New Delhi.



ADVANCED PHARMACOGNOSY-II PRACTICAL

Code: MPT-292
Contact: 4 hr per week
Credits: 2
Full Marks: 100

1. Isolation of piperine from pepper.
2. Estimation of piperine in pepper by UV, HPTLC, and HPLC Analysis.
3. Estimation of Total phenolic compounds from plant drugs.
4. Determination of total andrographolides from Kalmegh.
5. Determination of total bitters from the following plant drugs.
 - a) Kalmegh.
 - b) *Eclipta alba*.
 - c) Picrorhiza.
 - d) *Tinospora cordifolia*.
6. Estimation of total saponins from
 - a) *Bacopa monnieri*.
 - b) *Tribulus terrestris*.
7. Estimation of withanolides from *Withania somnifera*.
8. HPTLC estimation of Gugulosterones in Guggul.

SEMESTER - III

RESEARCH METHODOLOGY AND CLINICAL TRIALS

Code: MPT-314
Contact: 3 hr per week
Credits: 2
Full marks:

Information technology: subject classification and cataloguing, literature searches, data bases electronic and libraries, referencing and bibliographies, electronic communications.

- Good clinical practice.
- Good Laboratory Practice
- Ethics including consent and insurance
- Adverse drug reaction surveillance
- Randomization
- Clinical trial design
- Data management/statistics
- Protocol preparation
- Case record forms
- Evaluation of Reports and Report Writing
- International guidelines for Clinical Research
- Use of unregistered medicines for Research