JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY, KAKINADA

SYLLABUS for M.PHARMACY

PHARMACOGNOSY

I SEMESTER

Paper 101	**-**	**Modern Analytical Techniques**
Paper 102	**-**	**Research Methodologies**
Paper 103	-	**Advanced Pharmacognosy & Pytochemistry**
Paper 104	**-**	**Industrial Pharmacognosy**
Paper 105	**-**	**Advanced Pharmacognosy & Pytochemistry – LAB**
Paper 106	**-**	**Industrial Pharmacognosy – LAB**
Paper 107	**-**	**Seminar**

II SEMESTER

Paper 201	**-**	**Herbal Drug Technology & Formulation Development**
Paper 202	**-**	**Bioassays & Pharmacological Screening Methods**
Paper 203	**-**	**Indigenous Systems of Medicine**
Paper 204	**-**	**Drug Regulatory Affairs**
Paper 205	**-**	**Herbal Drug Technology & Formulation Development - LAB**
Paper 206	**-**	**Bioassays & Pharmacological Screening Methods - LAB**
Paper 207	**-**	**Seminar**

III SEMESTER

Paper 301	**-**	**Project Seminar-I (On the proposed project work with aims and objectives) - 50 Marks**
Paper 302	**-**	**Project work - I**

IV SEMESTER

Paper 401	**-**	**Project Seminar-II (On the experimentation and results of the project work) – 50 Marks**
Paper 402	**-**	**Project work - II**

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACOGNOSY

FIRST SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 103	Advanced Pharmacognosy & Pytochemistry	40	60			100	3
Paper – 104	Industrial Pharmacognosy	40	60			100	3
Paper – 105	Advanced Pharmacognosy & Pytochemistry – Lab			40	60	100	2
Paper – 106	Industrial Pharmacognosy - Lab			40	60	100	2
Paper – 107	Seminar					100	2
	TOTAL					700	18

SECOND SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Herbal Drug Technology & Formulation Development	40	60			100	3
Paper –202	Bioassays & Pharmacological Screening Methods	40	60			100	3
Paper – 203	Indigenous Systems of Medicine	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Herbal Drug Technology & Formulation Development – Lab			40	60	100	2
Paper – 206	Bioassays and Pharmacological Screening Methods - Lab			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

THIRD AND FOURTH SEMESTERS

Paper No.	III Semester	Total	Credits ***
Paper - 301	Project Seminar – I (On the proposed project work with aims and objectives)	50	2
Paper - 302	Project work - I	----	20
	Total	50	22

Paper No.	IV Semester	Total	Credits ***
Paper - 401	Project Seminar – II (On the Completed project work)	50	2
Paper - 402	Project work - II	---	20
	TOTAL MARKS	50	22
	GRAND TOTAL FOR THE COURSE	1500	80

M.PHARM - I SEMESTER

PAPER 101: MODERN ANALYTICAL TECHNIQUES

(Paper Common for all Specializations)

Principles, instrumentation and applications of the following Instruments and Chromatographic Techniques

Unit- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

Unit- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

Unit- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

Unit- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

Unit- V

i. Plasma Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapor phase chromatography
v. Affinity chromatography
vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scoog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy by Silversterin

PAPER 102: RESEARCH METHODOLOGIES

(Paper common for all Specializations)

UNIT - I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution. Error and its significance - Measures of Error - Control of Error in Experimental Investigations – Problem Solving.

UNIT - II

Correlation and Regression, Multiple Regression - Problem Solving

UNIT - III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test. Non-parametric tests - their applications in pharmacy research with examples – Problem Solving

UNIT - IV

Design of Experiments

Criteria of a good design with examples.

Principles - Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs - their applications in Pharmacy research with examples – Problem Solving

UNIT - V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research - Problem Solving.

Optimization Techniques: Optimization Techniques based on Factorial Experiments - Problem Solving.

Recommended Books:

1. Fundamentals of Biostatistics by Khan & Khanum, Ukaaz Publications, Hyderabad.
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others.
3. Remington's Practice of Pharmaceutical sciences, (Latest Edition).
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd).
5. Introduction to Biostatistics – A text book of biometry By Pranab Kumar Banerjee

PAPER 103: ADVANCED PHARMACOGNOSY & PHYTOCHEMISTRY

Unit – I

Medicinal Plants Cultivation

(a) General aspects involved in the cultivation of medicinal plants.

(b) Factors involved in production of crude drugs
(i) Exogenous (ii) Mineral supplements
(iii) Nutrients (iv) Growth regulators and inhibitors

(c) Pest/weed control. Study of pesticide and weedicides with special importance to natural origin.

(d) Systematic methods of cultivation and post harvest technology for medicinal plants cultivated in India.
Senna, Vinca, Ispagula, Opium, Acorus, Garcinia, Lemon grass, Aswagandha

Unit – II

Detailed phytochemical study of the following class of phytoconstituents.

(a)	Phospholipids	-	Biosynthesis of lipids, palmitic acid, prostaglandins
(b)	Terpenes and Triterpenoids	-	Camphor, Menthol, Artemisinin, Forskolin, Taxol, Azadirachta
(c)	Resins and related compounds	-	Cannabis, Ginger, Myrrh, Benzoin
(d)	Plant phenols	-	Phenyl propanoids, Capsaicin Podophyllotoxin, Rutin, Tannins Gossypin
(e)	Alkaloids	-	Nicotine, Atropine, Quinine, Emetine, Morphine, Reserpine, Caffeine
(f)	Glycosides	-	Anthraquinone glycosides, Cardiac glycosides, Saponin Glycosides
(g)	Steroids	-	Cholesterol, Vitamin A&D Diosgenin

Unit – III

Structure elucidation of important phytoconstituents belonging to different groups.

(a)	Alkaloids	:	Nicotine, Atropine, Morphine, Caffeine
(b)	Glycosides	:	Digitoxin
(c)	Steroids	:	Cholesterol
(d)	Terpenes	:	Camphor, Menthol, Cineole

Unit – IV

Marine Pharmacognosy

(a) Study of important bioactive agents including chemistry and uses.

(b) Definition, present status and classification of important bioactive agents from Marine Source.

Unit – V

Applications of UV, IR, ^{1}HNMR, 13CNMR and Mass Spectroscopy in the structural elucidation of Natural products.

Chromatographic applications (TLC, PC, HPLC, HPTLC, GLC) in the isolation,

separation and purification of Natural products

Recommended Books:

1. Organic Chemistry of Natural Products, Vol. 1 & 2.Gurudeep R.Chatwal.
2. Pharmacognosy – G.E. Tease and W.C. Evans.
3. Pharmacognosy – Tyler, Brady, Robbers
4. Modern Methods of Plant Analysis – Peech & M.V. Tracey, Vol. I to VII.
5. Phytochemistry – Vol. I to IV Miller Jan Nostrant Renhold.
6. Recent Advances in Phytochemistry – Vol. 1 to 4
   Scikel Runeckles – Appleton Century Crofts.
7. Chemistry of Natural Products – Vol. 1 onwards IWPAC.
8. Natural Products – Chemistry Nakanishi Golo
9. Natural Products – A Laboratory Guide, Raphaelkhan
10. The Essential Oils – Ernest Guenther – Robbert E. Kreiger 1)
    The Alkaloids Chemistry & Physiology – Vols. R.H.F. Manske
11. Introduction to Molecular Phytochemistry – Paul J. Schewer 1973.
12. Chemistry of Marine Natural Products – Paul J. Schewer 1973.
13. Marine Pharmacognosy Ed. By Dean F. Martin & George Padilla.
14. Marine Natural Products – Vol. I to IV.
15. Comparative Phytochemistry edited by T. Swain.
16. Chemical Plant Taxonomy edited by T. Swain
17. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
18. Cultivation and Utilisation of Aromatic Plants by C.K. Atal and B.M. Kapoor.
19. Plant Propagation Principles and Practices – Hertmann Kester
20. Ayurvedic Formulary of India, Government of India.
21. Glimpses of Indian Ethano-pharmacology by V.V. Pushpangadan.

PAPER 104: INDUSTRIAL PHARMACOGNOSY

UNIT – I

General methods of isolation, purification, identification and estimation of phytoconstituents.

Morphine, quinine, emetine, sennosides, volatile oils.

Unit – II

Different methods (including industrial) for the isolation and estimation of the following phytopharmaceuticals.

(a) Starch, (b) Caffeine, (c) Atropine, (d) Taxol, (e) Vinca alkaloids,

(f) Withaferin, (g) Ergometrine, (h) Morphine

Unit – III

Applications of HPLC and HPTLC in the isolation, separation and identification of natural products.

(a) Vasicine, (b) Bacoposide (c) Solasodine, (d) Lupeol

Unit – IV

Herbal based industries.

Study of infrastructure, regulatory requirements, research, patents and scope.

Commerce and quality control methods of crude drugs.

Unit – V

Study of herbal extracts

(a) Processing, (b) Plant and equipment, (c) Project profile

Study of the following herbal extracts for processing and standardisation

(a) *Withania somnifera*, (b) *Ocimum sanctum*,

(c) *Adathoda vasica* (d) *Centella asiatica*,

(e) *Melia azadirachta*

Recommended Books:

1. Pharmacognosy by G.E. Trease, W.c. Evans, ELBS.

2. Pharmacognosy by Varro E. Iylor, Lynn R. Brody, James E. Robberts, K.M. Varghese Co., Mumbai.

3. Text book of Pharmacognosy by T.E. Wallis, CBS Pub., Delhi.

4. Diosqenin and other Steroid Drug Precursors by Asolkar, CSIR.

5. Steroids by Feiry and Feisher.

6. Alkaloids Chemical and Biological by S.W. Pelletier.

7. Chromatography of Alkaloides by Vapoorte, Swendson.

8. Elements of Chromatography by P.K. Lala.

9. Jenkins Quantitative Pharmaceutical Chemistry by A.N. Knewell.

10. Clarke's Isolation and Identification o Drugs by A.C. Mottal.

11. Selected Topics in Exp-Pharmacology by Seth V.K.

12. Phytochemical Methods of Chemical Analysis by Harborne.

13. Organic Chemistry Vol. II by I.L. finar.

14. The Use of Pharmacological Techniques for the Evaluation of Natural Products by B.N. Dhavan, R.c. Srimal, CDRI, Lucknow.

15. Herbal Drugs Industry by R.D. Chaudhri.
16. Herbal Pharmacopoeia.
17. HPLC Methods of Drug Analysis by Mantu K. Ghosh.

PAPER 105: ADVANCED PHARMACOGNOSY & PYTOCHEMISTRY – LAB

I. Isolation, separation, purification and identification of important phytoconstituents

a) Starch from potatoes
b) Myristicin from nutmeg
c) Eugenol from clove
d) Curcumin from turmeric
e) Sennosides from senna
f) Glycyrrhizin from glycyrrhiza
g) Caffeine from tea

II. Quantitative microscopy

III. Spectral interpretation (UV, IR, NMR and Mass)

PAPER 106: INDUSTRIAL PHARMACOGNOSY – LAB

I. Chromatography of various classes of Phytoconstituents (PC, TLC, Column)

II. Evaluation of crude drugs

(a) Extractive values
(b) Moisture content
(c) Ash values
(d) Volatile oil content
(e) Percentage of active constituents

III. Spectroscopic analysis of plant constituents.

IV. Monographic analysis of crude drugs mentioned in IP.

V. Standardisation of herbal formulations.

II SEMESTER

PAPER 201: HERBAL DRUG TECHNOLOGY & FORMULATIONS DEVELOPMENT

Unit – I

Tissue culture

(a) Culture methods, (b) Organogenesis and embryogenesis,
(c) Micropropagation, (d) Haploid culture, (e) Synthetic seeds,
(f) Immobilisation

Unit – II

Production of secondary metabolites:

Strategies, use of precursors, growth regulators and elicitors, batch culture and continuous culture, applications of new culture methods, hairy root culture, biotransformation, production of secondary metabolites, taxol, ajmalcine, artemicin.

Mutation, hybridization, polyplady of medicinal plan and their applications.

Unit – III

Manufacturing of phytopharmaceuticals

(a) Strychnine, (b) Brucine, (c) Emetine, (d) Quinine, (e) Morphine,
(f) Cocaine, (g) Atropine, (h) Tannic acid, (I) Lemongrass oil,
(j) Sandalwood oil, (k) Clove oil, (l) Eucalyptus oil.

Oleoresins: capsicum, pepper, ginger, turmeric.

Unit – IV

i. Herbal cosmetics: Study of the cosmetic preparation including methods of preparation and standardisation.

(a) Shampoos, (b) Hair conditioners, (c) Hair dye, (d) Skincare products

Tracer techniques

Unit – V

Study of Herbal Formulation and their standardization.

PAPER 202: BIOASSAYS & PHARMACOLOGICAL SCREENING METHODS

Unit – I:

Principles of Experimental Pharmacology and Drug Discovery:

Common laboratory animals in Pharmacological research, Limitations of animal tests, Alternatives to animal use, Anesthetics used in laboratory animals, some standard techniques used in handling laboratory animals, Euthanasia of experimental animals. Regulation for the care and use of laboratory animals.

Strategies and approaches employed in drug discovery. Basic concepts of Combinatorial chemistry, High throughput screening, Cell lines and their applications in drug discovery. Transgenic animal models in the development of new drugs.

Unit – II:

Principles of Biological standardization: Statistical treatment of modern problems in the biological evaluation of drugs. Methods used in the bio-assays for antibiotics and microbiological assays. Bioassay for Diphtheria antitoxin; Tetanus; Cholera vaccine; Posterior Pituitary extract; Adrenaline; Heparin; Digitalis; d-Tubocurarine; Vitamins. Test for pyrogens.

Bioassay methods for autocoids – Development of new bio-assay methods. Assays using special designs for experiments to eliminate known source of variation. Toxicity tests, Determination of LD_{50}, Acute, Sub acute, and Chronic toxicity studies – Tests for freedom from undue toxicity of drugs.

Unit - III:

Basic Principles of Screening and types – Simple, Blind and Programmed Screening. Need for isolated tissues in pharmacological evaluation of drugs.

Organization of screening for the Pharmacological activity and evaluation of new substances in CVS:

1. Diuretics
2. Antihypertensives
3. Antianginal agents
4. Anti arrhythmic agents and agents used in sudden cardiac failure
5. Druigs used in cardiomyopathies
6. Drugs used in hyperlipidemia and atherosclerosis
7. Anti infarct agents

Unit - IV:

Organization of screening for the Pharmacological activity and evaluation of new substances in CNS:

1. Anti-epileptics
2. Anti-anxiety agents and Drugs used in mood and sleep disorders
3. Antipsychotics
4. Drugs affecting memory
5. Drugs used in Alzheimer's disease
6. Local Anesthetics
7. Skeletal muscle relaxants and Neuromuscular blockers

Unit - V:

Organization of screening for the Pharmacological activity and evaluation of new substances

1. Anti-diabetic agents
2. Analgesics and Drugs used in arthritis and neuropathic pain
3. Anti-Inflammatory agents
4. Anti-asthmatic agents
5. Anti-ulcer agents
6. Hepatoprotective agents

Recommended Books:

1. H.G.Vogel (ed),Drug Discovery and Evaluation- Pharmacological Assays,2nd Edition, Springer verlag,Berlin,Germany,2002.
2. M.N.Gosh, Fundamentals of Experimental pharmacology,2nd Edition, Scientific Book Agency,Culcutta,India,1985.
3. D.R.Laurence and A.L.Bacharach (Eds), Evaluation of Drug Activities: Pharmacometrics, Volume I and II, Academic press,London,U.K,1964.
4. Biological Standardization by J.H.Burn, D.J.Finney and L.G. Goodwin.
5. Pharmacopoeias: IP,BP,USP
6. Screening methods in pharmacology by Robert A.Turner.
7. Methods in Pharmacology by Swarbrick.

PAPER 203: INDEGINOUS SYSTEMS OF MEDICINE

UNIT I

Introduction to various systems of indegeneous medicine, principles and concept of ayurveda, history and development of ayurvedic medicine, influence of ayurvedic medicine on the scope and development of herbal drugs.

Approximate equivalence of dosage in Indian system and metric system. English equivalence of ayurvedic clinical conditions and diseases.

UNIT II

Definition and method of preparation of following ayurvedic formulations with their uses.

a) churnas: triphala churna,trikatu churna, hingvashtak churna.
b) Vati : chandraprabhavati, eladi vati, lavangadi vati
c) Taila: bala taila, bhringaraj taila, shatabindu taila

UNIT III

Definition and method of preparation of following ayurvedic formulations with their uses.

a) ghrita :brahmi ghrita, jhatyadhi grita, kshirashataphala grita
b) asavas –arishtas: chandan asava, dashamoolaarishta, kumari asava
c) swaras: amalaki swaras, nimbu swaras, tulsi swaras

UNIT IV

Clinical trails in ayurvedic formulations

Introduction to clinical trails – history terminologies, types of clinical research, phases of research, role of clinical trail in new drug development. Regulatory aspects related to manufacture and sale of ayurvedic formulations.

UNIT V

Principles of homeopathy, unani and siddha, systems of medicines, their merits and demerits. Introduction to different dosage forms and method of preparation of homeopathy and unani medicine.

Recommended / Reference books:

1. Ayurvedic formulary of India, Govt. of India
2. Homeopathic Pharmacopoeia
3. Unani Medical Systems
4. Pharmacopoeial standards for Ayurvedic formulations CCRAS, Delhi
5. Ayurvedic pharmacopoeia
6. Indian herbal pharmacopoeia Vol.1 and 2 RRL, IDMA
7. Standardization by Botanicals by V. RAJ PAL, Vol. 1, Eastern Publishers New Delhi
8. Healing plants of peninsular India by Parrota CABI Publications
9. Principles of integrated medicines by Mathur PR

PAPER 204: DRUG REGULATORY AFFAIRS:

(Paper Common for all Specializations)

Unit - I

Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections and ocular preparations as per the European community, United States and Indian regulatory authorities.

Unit - II

Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.

Unit - III

Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.

Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

Unit - IV

Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability , study design, presentation documentation and statistical analysis.

Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

Unit - V

Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations.

Recommended Books:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.
7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987

PAPER 205 - HERBAL DRUG TECHNOLOGY & FORMULATIONS DEVELOPMENT – LAB

I. Isolation, separation, purification and identification of important phytoconstituents

a) Starch from potatoes
b) Myristicin from nutmeg
c) Eugenol from clove
d) Curcumin from turmeric
e) Sennosides from senna
f) Glycyrrhizin from glycyrrhiza
g) Caffeine from tea

II. Quantitative microscopy

III. Spectral interpretation (UV, IR, NMR and Mass)

PAPER 206 - BIOASSAYS & PHARMACOLOGICAL SCREENING METHODS LAB

(Practicals based on theory)