



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., Act. No. 30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

Course Structure for B. Pharmacy. - R13 Regulations
B. Pharmacy

IV-I Semester

S.No	Course code	Subject	Th	Tu/Drg/Lab	Credits
1.	13R00701	Pharmacognosy-III	3	1 - -	3
2.	13R00702	Biopharmaceutics & Pharmacokinetics	3	1 - -	3
3.	13R00703	Pharmacology-III	3	1 - -	3
4.	13R00704	Medicinal Chemistry-III	3	1 - -	3
5.	13R00705 13R00706 13R00707	Choice Based Credit Course* (CBCC) 1. Chemistry of Natural Products 2. Clinical and Hospital Pharmacy 3. Pharmacovigilance	3	1 - -	3
6.	13R00708	Pharmacognosy-III Laboratory	-	- - 4	2
7.	13R00709	Biopharmaceutics & Pharmacokinetics Laboratory	-	- - 4	2
8.	13R00710	Pharmacology-III Laboratory		- - 4	2
9.	13R00711	Medicinal Chemistry-III Laboratory		- - 4	2
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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ANANTHAPURAMU**

Subject	PHARMACOGNOSY –III	Code	13R00701
Courseyear	B. Pharmacy IV year	Semester	I
Theory	3 hrs/week	Tutorial	1hr/week
End exam	70 marks	Internalexam	30 marks
Credits	3		

Scope: To study the phytochemical screening of plant materials, plant tissue culture, traditional drugs.

Objectives: To understand finger printing and marker compound analysis.

Outcomes: Student will acquire a knowledge on cosmetics, natural dyes, mineral drugs, Ayurvedic, Sidda, Unani and Hemeopathy

UNIT I

A) Phytochemical Screening: Preparation of extracts, screening of alkaloids, saponins, cardiac glycosides, flavonoids, tannins and anthraquinones in plant extracts. Identification and estimation of various phytoconstituents.

B) Plant tissue culture: History, types, media requirements, methodology for establishment of cell cultures; growth measurements, viability measurements and applications. Micropropagation, immobilization, hairy root culture.

UNIT II

Introduction, classification and study of different chromatographic methods and their applications in evaluation of crude drugs. Concept of finger printing and marker compound analysis.

UNIT III

A) Study of traditional drugs - common and vernacular names, sources, chemical constituents and uses of Kantakari, Malkanguni, Shatavari, Tylophora, Bilva, Kalijeeri, Rasna, Aparmarga, Gokhuru, Guduchi, Bach, Amla, Guggul, Kalimusali, Punarnava, Chirata and Brahmi.

B) General introduction to Indian Systems of Medicine like Ayurveda, Siddha, Unani and Homeopathy.

C) Methods of preparation of formulations in Ayurveda like churnas, lehyas, tailas, asavas and aristas.

UNIT IV

A) General introduction to cosmeceuticals, role of herbs in cosmetics. Study of the following cosmeceuticals - Amla, Henna, Cyperus, SoapNut, AloeVera, Turmeric, Sandal Wood and Bitter Orange Peel.

B) Definition and study of Neutraceuticals: Garlic, Spirulina, Soya and Royaljelly.

C) Introduction and importance of trade in herbal medicine, herbal cosmetics and Indian herbal drug industry.

UNIT V

A) Natural dyes and their applications in pharmacy.

B) Study of mineral drugs - Bentonite, Kaolin, Keiselghur and Talc

C) Study of natural products from natural sources

TextBooks:

1. Kokate CK, Purohit A.P. & Gokhale; Pharmacognosy Nirali Prakashan, New Delhi.
2. Textbook of Pharmacognosy by Handa and Kapoor.
4. Pharmacognosy by Robert, Tyler.

ReferenceBooks:

1. WHO guidelines on good agricultural and collection practices (GACP)-WHO, Geneva
2. Cultivation & utilization of medicinal plants by Atal CR and Kapoor BM.
3. Textbook of Pharmacognosy by Wallis.
4. Pharmacognosy by Trease and Evans, latest edition.
5. USP, IP and BP. Ayurvedic Pharmacopoeia of India.
6. Ayurvedic Pharmacopoeia of India, Published by Govt of India.
7. Herbal Drug Industry by Eastern Publishers.
8. Peach Kand Tracey MV, Modern methods of Plant analysis, Narose publishing house, New Delhi.
9. Ayurvedic Formulary of India, Govt of India Publication.
10. The Wealth of India, All volumes, CSIR, New Delhi.
11. Harbone JB; Phytochemical methods, Chapman and Hall.
12. Plant Tissue culture By Razdan

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	BIOPHARMACEUTICS AND PHARMACOKINETICS	Code	13R00702
Course Year	B. Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30Marks
Credits	3		

Scope: This subject will provide an opportunity for the student to learn about the Biopharmaceutics and pharmacokinetic.

Objective:

- The course is designed to explore the knowledge in ADME.
- The course helps to learn significance of plasma drug concentration measurement.

Outcomes:

1. Graduate will acquire knowledge on the factors influencing absorption, distribution, protein binding and also on pharmacokinetic models.
2. Able to calculate the pharmacokinetic parameters based on plasma level-time data & urine data.
3. Understand the importance of clinical pharmacokinetics and the bioavailability and bio equivalence studies.

UNIT – I

Biopharmaceutics, Pharmacokinetics and Pharmacodynamics. Structure of GI membrane. Routes of drug administration and absorption from different routes.

Drug Absorption. Mechanisms of GI absorption, physico-chemical, biological and dosage form factors influencing absorption.

Drug distribution. Factors affecting drug distribution, physiological barriers of drug diffusion, apparent volume of distribution, drug binding to blood, tissues, protein binding – factors affecting, significance and kinetics of protein binding.

UNIT – II

Drug Metabolism: Pathways of drug metabolism. Phase-I (oxidative, reductive and hydrolytic reactions). Phase II reactions (conjugation) Enzyme induction and inhibition, hepatic clearance, pharmacological activity of metabolites, first pass effect.

Drug excretion. Glomerular filtration, tubular secretion and reabsorption, effect of pH and other drugs. Clearance concept, excretion through bile, feces, lungs and skin in brief.

UNIT – III

Bioavailability and bioequivalence: concept of equivalents, Definitions of various types of equivalents, types of Bioavailability studies, measurement of Bioavailability, plasma level and urinary excretion studies. Bioequivalence study design, IVIVC.

UNIT – IV

Pharmacokinetics. Basic considerations, compartment modeling, one compartment open model - i.v. bolus and extra vascular administration, urinary excretion studies. Apparent volume of distribution, elimination rate constant, biological half life, area under the curve and clearance. Calculation of pharmacokinetic parameters. Method of residuals, Wagner and Nelson method , excretion rate method, sigma minus method. Solving of simple problems

UNIT – V

Nonlinear kinetics. Non compartmental models, reasons for non linearity, concepts of linearity and non linearity, Michaelis- Menten equation and its significance.

Text Books:

1. L. Shargel and ABC Yu, *textbook of applied biopharmaceutics & Pharmacokinetics*, 4th edn, Appleton – century – crofts, Connecticut, 2004.
3. Milo Gibaldi, *Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book Syndicate.Hyderabad.*
4. DM Brahmankar and SB Jaiswal, *biophamaceutics and pharmacokinetics- a treatise*, vallabh prakasham, Delhi.

Reference Books:

1. Ronald & trouser. *Clinical pharmacokinetics concepts & applications*. 3rd ed, wolterskluwer Pvt Ltd., 2007.
2. Robert E notary, *Biopharmaceutics and pharmacokinetics – an introduction*, marcel dekker inc., NY
3. *Basic pharmacokinetics* by Hedaya, CRC press.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	PHARMACOLOGY – III	Code	13R00703
Course Year	B.Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30Marks
Credits	3		

Scope: This subject will provide an opportunity for the student to learn pharmacological information about the drugs. In this subject drugs acting on gastrointestinal system, chemotherapeutic agents, principles of toxicology and bioassays will be taught.

Objectives: Upon completion of the subject student shall be able to

Understand various pharmacological aspects like mechanism of action, pharmacokinetics, side effects, drug interactions, contraindications and indications of drugs falling under below mentioned chapters.

Outcomes:

- a. Correlate and apply the knowledge.
- b. Handle the animals and carry out the experiments on animals
- d. Understand the chemotherapy of various diseases

UNIT I

Drugs acting on the gastrointestinal tract

- a. Anti-ulcers Drugs
- b. Laxatives and anti-diarrhoeal drugs
- c. Emetics and anti-emetics
- d. Appetite Stimulants and Suppressants

UNIT II

Chemotherapeutic agents and their applications

- a. General principles of chemotherapy.
- b. Sulphonamides, co-trimoxazole and β -lactam antibiotics
- c. Tetracyclines, aminoglycosides, chloramphenicol, macrolides, quinolones, fluoroquinolones and polypeptide antibiotics

UNIT III

- a. Chemotherapy of tuberculosis & leprosy
- b. Chemotherapy of malignancy and immunosuppressive agents.

UNIT IV

- a. Chemotherapy of fungal and viral diseases
- b. Chemotherapy of protozoal diseases and helminthic infections

UNITV

Principles of toxicology & Principles of bioassays.

- a. Definition of poison, general principles of treatment of poisoning
- b. Treatment of barbiturate, opioid, organophosphorous and atropine poisoning.
- c. Heavy metals and heavy metal antagonists. LD_{50} , ED_{50} and therapeutic index
- d. Principles of bioassays and errors in bioassays.
 - d. Study of bioassay methods for the following drugs
 - i. Digitalis

d-tubocurarine,

iii. Oxytocin iv. Insulin v. HCV

ii.

Text Books:

1. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4th Ed.
2. J.G. Hardman and Lee E. Limbard, Good Mann & Gilman, The Pharmacological basis of therapeutics, Mc Grawhill, Health Professions Dvn.
3. Illiterated Pharmacology by Lippincotts

REFERENCES

1. Tripathi, Essentials of Medical Pharmacology, Jaypee Brother's, Latest Edition
2. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	MEDICINAL CHEMISTRY -III	Code	13R00704
Course Year	B.Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30Marks
Credits	3		

Scope: This subject will provide an opportunity for the student to learn medicinal chemistry information about the drugs. In this subject student will be able to understand the properties and its biological activity of the drugs.

Objectives: Upon completion of the subject student shall be able to

1. Understand various drugs structure, their properties and biological activities.
2. Correlate and apply the knowledge.
3. Influence of chemical structure on biological activities.

Outcomes:

1. Acquire skill in the structure of drugs and their biological activities.
2. Acquire the knowledge of synthesis of chemical compounds.
3. Assay of some official compounds.

UNIT I

Histamine and Antihistaminic agents- H1-Antagonists: Chlorpheniramine*, Triprolidine, Phenindamine, Diphenhydramine*, Doxylamine succinate, Tripeleminamine, Antazoline phosphate, Cyclizine, Meclizine*, Buclizine, Promethazine*, Methdilazine, Cyproheptadine, Azatadine maleate, Fexofenadine, Loratadine, Desloratadine, Cetzine, Acrivastin, H2 Antagonists: Cimetidine, Famotidine, Ranitidine*, Omeprazole*, Esomeprazole, Lansoprazole, Pantoprazole, Rabeprazole, Sucralfate, Misoprostol. Note on H3-Agonist and antagonists. SAR – H1 and H2 receptor antagonists.

UNIT II

Synthetic antibacterials and antifungal agents Sulphonamides and quinolones: Cotrimaxazole, Sulphacetamide*, Sulphaquanidine, sulfisoxazole*, sulfadoxime, trisulfapyrimidines, triple sulfa, Norfloxacin, Ciprofloxacin, Ofloxacin*, Levofloxacin. SAR- Sulphonamides, Fluroquinolones. Urinary antiseptics: Nitrofurantoin*, Furazolidine, Nitrofurazole, Methenamine. Antifungal agents: Clotrimazole*, Itraconazole, Ketoconazole, Miconazole*, Fluconazole, Amphotericin B, Nystatin, Griseofulvin*. SAR- azoles.

UNIT III

Anti-parasitic and antimycobacterial agents Antimalarials: Life cycle, Chloroquine*, Amodiaquine, Primaquine, Quinacrine*, Artemisinin, Pyrimethamine, Atovaquone and Proguanil. SAR – 4-aminoquinolines, Aminoacridines. Antiamoebics and anthelmintics: Metronidazole, Tinidazole*, Diloxanide, Iodoquinol, DEC*, Thiabendazole, Piperazine, Mebendazole*, Albendazole, Dimercaprol, Niclosamide, Pyrantel Pamoate, Ivermectin. SAR- Azole Antimycobacterials: Isoniazid*, Ethambutol*, Pyrazinamide, Rifampicin, Thioacetazone, 4-Asa Cycloserins, Dapsone*, Clofazimine.

UNIT IV

Antiviral and antineoplastic agents Antiviral: Viral replication, Amantidine*, Acyclovir*, Oseltamivir, Idoxuridine, Zidovudine*, Lamivudine, Stavudine, Efavirenz, Didanosine, Tenofovir, Zalcitabine, Emetricitabine, Nevirapine, Ritonavir, Saquinavir. SAR- RTIs, NNRTIs. Antineoplastic: Chlorambucil*, Cyclophosphamide, Ifosamide, Thiopeta, Lomustine, Busulfan, Carmustine*, Cisplatin, Procarbazine, Streptazocin, Methotrexate, 5-FU, Cytarabine, 6-Mp, Thioguanine, Vidarabine, Tamoxifen. Chemistry of anticancer antibiotics, A note on Newer agents. SAR – Alkylating agents, Nitroso ureas, Antimetabolites.

UNIT V

Basic concepts of Drug Design and discovery Concept on ligand, targets, lead molecules, Pharmacophore. Basis of structure based and ligand based drug design, note on Combinatorial chemistry, SAR, QSAR. Stereochemistry in drug design with suitable examples.

NOTE: Introduction, definition, chemical classification with structure, nomenclature, synthesis (only for * marked drugs), mechanism of action, SAR including stereo chemical aspects, metabolites (including its ADR) and therapeutic uses of the following classes of drugs from UNIT I to UNIT IV.

Text Books:

1. *JH Block & JM Beale (Eds), Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcolt, Raven, Philadelphia, 2004*
2. *William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.*
3. *An Introduction to Medicinal Chemistry by Graham. L. Patrick, Oxford University publishers.*
4. *Rama Rao Nadendla, Medicinal Chemistry; Mc Millan Publishers.*

Reference Books:

1. *Hansch, Comprehensive medicinal chemistry, Vol:1–6 Elsevier pergmon press, Oxford.*
2. *D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & 2. John Wiley & Sons, New York 2003, 6th Ed.*
3. *M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry Ed: 1. Oxford University Press, Delhi.*
4. *Daniel lednicer, Strategies for Organic Drug Synthesis and Design*

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	CHEMISTRY OF NATURAL PRODUCTS (CBCC)	Code	13R00705
Course Year	B.Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30Marks
Credits	3		

Scope: To Study the Phytochemical evaluation and Synthesis of natural Products

Objectives: To identify the structure and screening of the natural products

Outcomes: Acquire the skills in determination of structure, mechanism of action and uses of Natural products.

UNIT I

General structural elucidation of natural products General extraction procedure for various phytoconstituents, techniques in identification for alkaloids, glycosides, steroids, terpenes, flavonoids, phenols, lignans, resins, carbohydrate and proteins. Chemical methods for determination of active hydrogen, methoxy, hydroxyl, N-methyl and degradation (Hoffmann, Edmann etc) techniques for the determination of ring size. Structural elucidation of Ephedrine, Atropine, Morphine, Papaverine.

UNIT II

Alkaloids Definition of alkaloids, pseudoalkaloids and protoalkaloids. General methods of extraction, isolation, Properties and tests for alkaloids.

Opium alkaloids: Structural features of Morphine molecule – Peripheral groups. Modification of structure and effect on analgesic activity – SAR of morphine and morphine-like analgesics.

Narcotic antagonists: Nalorphine, Levallorphan. Anti-tussive agents: Noscapine, Dextromethorphan. Smooth muscle relaxants: Papaverine and related compounds like ethaverine, Dioxyline. Structures and uses of these compounds.

Tropane alkaloids: Structures of Atropine/hyoscyamine, Hyoscyne, Hydrolytic products of these – Tropine and Scopine. Relationship between tropine & pseudotropine. Biological actions and uses of tropane alkaloids. Homatropine.

Rauwolfia alkaloids: Structures and uses of Reserpine, Rescinnamine, Deserpidine, ajmaline, syrosingapine. Hydrolysis of reserpine and rescinnamine. Mechanism of action of reserpine.

Ergot alkaloids: Classification, structures, hydrolytic products, pharmacological actions, therapeutic uses and toxicity. Synthetic derivatives: Methyl ergonovine (Methyl ergometrine), LSD, Ethersergide.

UNIT III

Terpenes & Terpenoids: Introduction to Volatile oils, terpene vs terpenoids, Classification, isoprene, special isoprene and gemdialkyl rules. Sources and structures (Including isomerism), general extraction procedure and Pharmaceutical uses for Citral, citral-a (Geranial), citral-b (Neral). Alpha-terpeniol, Carvone, Menthol, Menthone, 1,8Cineole, Camphor. Chemical transformation and interconversion of citral to citronellal, citronellol, geraniol, nerol, geranic acid, p-cymene, alfa-terpeneol and ionones. Conversion and interconversion of camphor into camphoric acid, camphoronic acids, p-cymene, Borneol, isoborneol.

UNIT IV

Steroids: Introduction, nomenclature and classification of steroids. Stereochemistry of Cholesterol. Structure and uses of Bile acids, steroidal hormones. Different Sources of steroidal drugs like diosgenin, cholesterol, stigmasterol and ergosterol. synthesis of progesterone and testosterone. Synthetic oestrogens like diethyl stilbesterol, hexosterol, 17-alpha ethinyl oestradiol, Interconversions of Estrone, Estriol, Estradiol. Chemistry of keto and non keto adreno corticoids. A note on anabolic steroids (Structure and uses).

Cardiac glycosides: structures of glycosides from Digitalis, Strophanthus, Squill and Bufo. Enzymatic and acid hydrolytic reactions of the glycosides. Mechanism of action, SAR, therapeutic uses and toxicity.

UNIT V

Vitamins: Classification, structure and related function in enzyme and physiological activity. Chemistry of thiamine, riboflavin, Niacin, Pyridoxine, Vitamin A, D, E, K. structural elucidation of Riboflavin, Vitamin D.

Text Books:

- 1) JB Harborne, *Phyto Chemical methods*. Springer.
- 2) I L Finar, *Organic chemistry, Vol. 1 & 2, the English language book society, London, New Delhi*.
- 3) O.P. Agarwal, *Natural products by. Vol.1 & 2, Goel publications – Meerut*.

Reference Books:

1. RT Morrison and R.N Boyd, *Organic chemistry, Allyn and Bacon, inc., boston*
2. Me –Wolf, ed., *Burger''s medicinal chemistry, J. Wiley & sons, NY*.
3. F.G. Mann & B. Saunders, *Practical Organic chemistry Longmans green & Co. Ltd., UK*.
4. RM. Acheson, *an introduction to the chemistry of heterocyclic compounds, Interscience NY*.
5. Duquesn & others, *Practical pharmacognocny, CBS Publ.*

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	CLINICAL AND HOSPITAL PHARMACY (CBCC)	Code	13R00706
Course Year	B.Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30Marks
Credits	3		

Scope: To acquire the Knowledge about Clinical Procedures and study of case reports.

Objectives: Patient counseling and Dispensing of Drugs and identification of drug interactions in Prescriptions.

Outcomes: To council the patients about usage of drugs and drug interactions

UNIT I

Introduction to clinical pharmacy:

- Prospects and perspectives of clinical pharmacy in national and international scenario, scope of clinical pharmacy
- Therapeutic Drug Monitoring.
- Clinical Pharmacokinetics and individualization of Drug Therapy.
- Concept of Essential Drugs and Rational Drug use.

UNIT II

Introduction to daily activities of Clinical pharmacist

- Drug therapy monitoring (Medication chart review)
- Adverse Drug Reactions & Drug Interactions
- Patient counseling
- Drug and poison information.
- Ward round participation.

UNIT III

Clinical laboratory tests and interpretation of test results.

- Hematological (complete blood picture)
- Pulmonary function tests
- Tests associated with cardiac disorders
- Liver, Renal function tests

UNIT IV

Hospital Management

Organization of a hospital and hospital pharmacy (drug store), responsibilities of a hospital Pharmacist, pharmacy and therapeutic committee. Hospital formulary, purchase and inventory control, role of Pharmacist in community health care and education.

UNIT V

Drug distribution and records

Procedural manual, drug distribution, dispensing to out-patients, in-patients and ambulatory patient dispensing of ancillary and controlled substances. Prescription filling, drug profile.

Text Books:

- A Textbook of clinical pharmacy practice: Essential concepts and skills. Dr G Parthasarathi et al. Orient Longmannpvt ltd. ISSN: 8125026*
- Leon shargel, comprehensive pharmacy review, Latest Edition*
- Health Education and Community Pharmacy, Gupta AK, CBS, Publ. and Distributors New*

Delhi – (2010).

Reference Books:

1. *J.G. Hardman and Lee E. Limbard, Good Mann & Gilman, The Pharmacological basis of therapeutics, Mc Grawhill, Health Professions Dvn.*
2. *Health Education and Community Pharmacy, NK Jain, CBS, Publ. and Distributors New Delhi.*
3. *Hospital pharmacy by Hassan.*

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	PHARMACOVIGILANCE (CBCC)	Code	13R00707
Course Year	B.Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30Marks
Credits	3		

Scope: To study Adverse effects and monitoring of adverse Drug Reactions

Objectives: To Identify the Adverse drug reactions and surveillance of Reports.

Outcomes: Should have the Knowledge about the terminology of adverse medication related events, roles and responsibilities in Pharmacovigilance.

UNIT –I

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring / Why Pharmacovigilance

National and international scenario

- Pharmacovigilance in India
- Pharmacovigilance global perspective
- WHO international drug monitoring programme

UNIT –II

Basic terminologies used in Pharmacovigilance

- Terminologies of adverse medication related events
- Information resources in Pharmacovigilance

Establishing Pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Establishing a national programme
- SOPs – Types, designing, maintenance and training
- Roles and responsibilities in Pharmacovigilance

Licence Partners, Contract Research Organisations (CROs) and Market Authorisation Holders (MAH)

UNIT –III

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study

UNIT –IV

Adverse drug reaction reporting

- Introduction to reporting systems
- Spontaneous reporting system
- Reporting to regulatory authorities
- Guidelines for reporting ADRs in biomedical literature

UNIT –V

Communication in Pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities &Media, Dear Doctor Letters to Healthcare Professionals

TEXTBOOKS

1. Textbook of Pharmacovigilance by S.K. Gupta, Jaypee brothers.
2. Pharmacovigilance by Ronald D. Mann, Elizabeth B.Andrews, 2nd edition.

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	PHARMACOGNOSY –III LABORATORY	Code	13R00708
Course year	B. Pharmacy IV year	Semester	I
Practical	4hrs/week	Tutorial	NIL
End exam	50 marks	Internal	25 marks
credits	2		

Scope: To study the Preparation and evaluation of plant materials.,

Objectives: To Identify the impurities of plant materials.

Outcomes: Should have the Knowledge about the Phytoconstituents of the plants and Phytochemical screening of the plant materials

I.EXPERIMENTS:

1. Determination of moisture content.
2. Determination of Ash values, water soluble ash, acid insoluble ash.
3. Determination of extractive values.
4. Isolation of quinine from Cinchona
5. Isolation of vasicine from Vasaka leaves.
6. Preparation of herbal formulations like, herbal syrups,
7. TLC of any one alkaloid and one glycoside.
8. Preparation and evaluation of any one herbal cosmetic. churnas and the like.
9. Preparation and evaluation of any one Ayurvedic formulation.
10. Phytochemical screening of a plant material.
11. Paper chromatography of any one type of phytoconstituents.

II.DEMO/WORKSHOP:

Column chromatography of plant extract, estimation of any one phytoconstituent by Modern chromatographic methods.

III.SEMINAR/ASSIGNMENT/GROUP DISCUSSION:

Related to theory syllabus

Text Books:

1. *Practical Pharmacognosy.* -C.K.Kokate Nirali Prakashan
2. *Practical Pharmacognosy*-Iyengar Manipal press limited

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Waterbath
2. Hotplates
3. Soxhlet extractor
4. Microscopes
5. Glass slides
6. Muffle furnace
7. Incinerator
8. Crucible
9. Colorimeter
10. Analytical balance
11. Heating mantle
12. Adequate glassware

REFERENCES

1. *Practical Pharmacognosy, CK Kokate, Nirali Prakashan*
2. *Practical Pharmacognosy, Khandelwal, Nirali Prakashan*
3. *Practical Pharmacognosy Iyengar, Manipal Press Ltd.*
4. *Brain KR and Turner TD. The practical Evaluation of Phytopharmaceuticals, Wright-Scien technics, Bristol.*
5. *Indian Pharmacopoeia. 1966.*
6. *Peach K and Tracey MV, Modern methods of Plant analysis, Narose publishing house, New Delhi.*

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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Subject	BIOPHARMACEUTICS AND	Code	13R00709
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	PHARMACOKINETICS LABORATORY		
Course Year	B.Pharmacy IV year	Sem	I
Lab	4hrs/week	Tutorial	Nil
End exam	50 Marks	Internal exam	25Marks
Credits	2		

Scope: This subject will provide an opportunity for the student to learn about the Biopharmaceutics and pharmacokinetic.

Objective:

- The course is designed to analysis of biological samples for drug content.
- The course helps to estimation of the pharmacokinetic parameters.

Outcomes:

1. Graduate will acquire knowledge on analysis of biological samples for drug content.
2. Able to calculate the pharmacokinetic parameters based on plasma level-time data & urine data.
3. Understand the statistical treatment of pharmaceutical data.

I. EXPERIMENTS

- 1) Analysis of biological samples for drug content and estimation of the pharmacokinetic parameters.
- 2) *In vitro* evaluation of tablet/capsule for drug release
- 3) Drug-protein binding studies.
- 4) Statistical treatment of pharmaceutical data.
- 5) Problems related to pharmacokinetics – determination of PK Parameters
- 6) Problems related to bioavailability and bioequivalence.

II. DEMO/ WORKSHOP

1. Absorption studies – *in vitro*.
2. Experiments designed for the estimation of various pharmacokinetic parameters.

III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION

Chronopharmacokinetics.

Text Books:

1. L. Shargel and ABC Yu, *textbook of applied biopharmaceutics & Pharmacokinetics, 4th edn, Appleton – century – crofts, Connecticut, 2004.*
3. Milo Gibaldi, *Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book Syndicate.Hyderabad.*
4. DM Brahmankar and SB Jaiswal, *biophamaceutics and pharmacokinetics- a treatise, vallabh prakasham, Delhi.*

Reference Books:

1. Ronald & trouser. *Clinical pharmacokinetics concepts & applications. 3rd ed, wolterskluwer Pvt Ltd., 2007.*
2. Robert E notary, *Biopharmaceutics and pharmacokinetics – an introduction, marcel dekker inc., NY*
3. *Basic pharmacokinetics by Hedaya, CRC press.*

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ANANTHAPURAMU**

Subject	PHARMACOLOGY - III LABORATORY	Code	13R00710
Course Year	B.Pharmacy IV year	Sem	I
Practical	3hrs/week	Tutorial	NIL
End exam	50 Marks	Internal exam	25 Marks
Credits	2		

Scope:

- a. To find out the drugs that is beneficial in clinics.
- b. Study the mechanism of Action and Site of action and their toxicities.
- c. Study the actions of drugs existing in Preclinicals

Objectives:

To know and understand pharmacological investigation techniques applied in the research

Outcomes:

1. Acquires ability to apply experimental approaches in characterization of drugs.
2. Able to use the knowledge to screen novel drugs in different animal models.

A. EXPERIMENTAL PART

1. Experiments on Isolated Preparations:
 - a. Calculate the PA_2 value of atropine using acetylcholine as an agonist on rat ileum preparation.
 - b. Calculate the PA_2 value of chlorpheniramine using histamine as an agonist on guinea pig ileum preparation.
 - c. Find out the strength of the given sample (e.g. Acetylcholine, Histamine, 5-HT, Oxytocin etc.) using a suitable isolated muscle preparation by
 - i. Interpolation bioassay
 - i. Matching or bracketing bioassay
 - iii. Three point bioassay
 - iii. Four point bioassay
2. Experiments on intact animals like
 - a. Study of drug induced catatonia in rats
 - b. Study of muscle relaxant activity (rotarod apparatus)
 - c. Study of antipsychotic activity (pole climb response apparatus)
 - d. Study of antianxiety activity (elevated plus maze)
 - e. Study of analgesic activity (analgesiometer)
 - f. Study of anti-inflammatory activity (plethysmometer)
 - g. Study of antidepressant activity (swim test & tail suspension test)
 - h. Study of anticonvulsant activity (electroconvulso meter)
 - i. Study of spontaneous motor activity and locomotor activity (actophotometer)

B. DEMO/ WORK SHOP

- a. Screening of antiulcer activity
- b. Invitro antioxidant activity
- c. Screening of antihistaminic activity (histamine chamber)

C. SEMINAR/ ASSIGNMENT/ GROUP DISCUSSION

- a. BABE studies
- b. Invitro-invivo correlation studies
- c. Pharmacovigilance
- d. Biostatistics and its application

REFERENCES

1. Practicals in pharmacology By Dr.R.K.Goyal
2. Handbook of experimental pharmacology By S.K.Kulakarni
3. Experimental pharmacology By M.N.Ghosh
4. Experimental Pharamcology and Toxicology By Dr.B.M.VrushabendraSwamy and Prof.K.N.Jayaveera, S.Chand& Co.,

Subject	MEDICINAL CHEMISTRY-III LABORATORY	Code	13R00711
Course Year	B. Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	NIL
End exam	50 Marks	Internal exam	25 Marks
Credits	2		

Scope: This subject will provide an opportunity for the student on synthesis of various compounds.

Objectives: Upon completion of the subject student shall be able to

- a. Synthesis various chemical compounds.
- b. Provide knowledge on monograph analysis of some chemical compounds.

Outcomes:

1. Acquire skills in synthesis various chemical compounds.
2. Demonstrate of stereo models of some drugs relevant to theory.
3. Acquire skills of extraction of drugs from different dosage forms.

I. EXPERIMENTS:

1. Synthesis of hydrazones of benzoic acid
2. Synthesis of Eosin from Fluorescein
3. Synthesis of benzilic acid from benzil
4. Synthesis of Sulphanilamide
5. Synthesis of 1,4- naphthaquinone from naphthalene
6. Synthesis of ortho iodo benzoic acid from anthranilic acid
7. Synthesis of Diazo amino benzene from aniline
8. Synthesis of acid hydrazides from salicylic acid
9. Synthesis of chalcones
10. Assay of Sulpha methoxazole (anti bacterial)
11. Assay of Glibenclamide (hypoglycaemic agent)
12. Assay of Metronidazole (antiprotozoal)
13. Assay of Isoniazid (anti tubercular)
14. Assay of Diethylcarbamazine (antihelmentic)
15. Assay of Compound benzoic acid (anti fungal)

II. DEMO/WORKSHOP

Vacuum drying, Chemdraw, Chems sketch, Recrystallization process, Separation of ternary mixtures

III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION

Water in phase transfer catalysis, Current topics on Cancer, Antibiotics, Anti-oxidants and chemotherapy of infectious diseases.

References:

1. A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition. Pearson, Prentice Hall.
2. F.G. Mann & B.C. Saunders, Practical Organic Chemistry, 4th Edition, Pearson Publishers.
3. I.P. – 1996.
4. P.D.Sethi – Quantative Analysis of Drugs in Pharmaceuticals. Formulations, CBS Publishers.
5. B.P. - 2004.

List of minimum EQUIPMENTS required

1. Water bath
2. Suction pumps
3. Analytical/physical balance
4. Triple beam balance
5. Reflux flask with condenser
6. Hot plates
7. Refrigerator
8. Mechanical and magnetic stirrer with thermostat
9. Distillation unit
10. Oven
11. Adequate glass wares