

**R15**
**B.Pharm IV-I Semester**

S. No.	Course Code	Subject	L	T	P	C
1.	15R00701	Novel Drug Delivery Systems	3	1	-	3
2.	15R00702	Pharmacology -III	3	1	-	3
3.	15R00703	Clinical and Hospital Pharmacy	3	1	-	3
4.	15R00704	Medicinal Chemistry-II	3	1	-	3
5.		<b>CBCC-II</b>	3	1	-	3
	15R00705	1.Chemistry of Natural Products				
	15R00706	2. Computer Aided Drug Design				
	15R00707	3. Pharmacovigilance.				
6.	15R00708	Novel Drug Delivery Systems Laboratory	-	-	4	2
7.	15R00709	Clinical and Hospital Pharmacy Laboratory	-	-	4	2
8.	15R00710	Medicinal Chemistry-II Laboratory	-	-	4	2
Total:			15	5	12	21

**R15**
**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>NOVEL DRUG DELIVERY SYSTEMS</b>	<b>Code</b>	<b>15R00701</b>
<b>Course year</b>	<b>B. Pharm IV year</b>	<b>Semester</b>	<b>I</b>
<b>Theory</b>	<b>3 hrs/week</b>	<b>Tutorial</b>	<b>1hr/week</b>
<b>End exam</b>	<b>70 marks</b>	<b>Internal exam</b>	<b>30 marks</b>
<b>Credits</b>	<b>3</b>		

**Scope:** The novel drug delivery systems course provide the knowledge about various novel and targeted systems- formulation, evaluation and applications

**Objectives:** To learn the novel technologies in drug delivery systems

**Outcomes:** Student must able to formulate the drug delivery systems for drugs.

**UNIT I**

Concepts of controlled release, sustained release, extended release, timed release and delayed release. Rationale behind the design of above delivery systems. Factors influencing the design and performance of sustained and controlled release dosage forms.

**UNIT II**

**Oral Control Drug Delivery Systems:** Fundamentals, Dissolution Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems, altered density systems and use of polymers in controlled drug delivery.

**UNIT III**

**Targeted Drug Delivery Systems:** Fundamentals and applications, formulation and evaluation of nano particles, resealed erythrocytes and liposomes and niosomes.

**UNIT IV**

**Transdermal Drug Delivery Systems:** Fundamentals, permeation of drugs across the skin, types of TDDS, Materials employed and Evaluation of TDDS.

**UNIT V**

**Mucoadhesive Delivery Systems:** Mechanism of bioadhesion, mucoadhesive materials, formulation and evaluation of Buccal and Nasal drug delivery systems.

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**R15****Text Books:**

1. Robinson JR and Vincent HL. Controlled drug delivery fundamentals and applications, 2ed, marcel dekker 2005.
2. YiewChien, Novel drug delivery systems, 2<sup>nd</sup>ed, marcel dekker 2003.

**Reference Books:**

1. N.K. Jain, Advances in Control & Novel drug delivery, CBS Publishers.
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
3. E.A Rawlins, Bentley's Text Book of Pharmaceutics, Elbspubl

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>PHARMACOLOGY – III</b>	<b>Code</b>	<b>15R00702</b>
<b>Course Year</b>	<b>B.Pharmacy IVyear</b>	<b>Sem</b>	<b>I</b>
<b>Theory</b>	<b>3hrs/week</b>	<b>Tutorial</b>	<b>1hr/week</b>
<b>End exam</b>	<b>70 Marks</b>	<b>Internal exam</b>	<b>30Marks</b>
<b>Credits</b>	<b>3</b>		

**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, sideeffects, drug interactions, contraindications and indications of drugs falling under below mentioned chapters.

**Outcomes:**

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

**UNIT I. Drugs acting on the gastrointestinal tract**

- Anti-ulcers Drugs
- Laxatives and anti-diarrhoeal drugs
- Emetics and anti-emetics
- Appetite Stimulants and Suppressants

**UNIT II. Chemotherapeutic agents and their applications**

- General principles of chemotherapy.
- Sulphonamides, co-trimoxazole and  $\beta$ -lactam antibiotics
- Tetracyclines, aminoglycosides, chloramphenicol, macrolides, quinolones, fluoroquinolones and polypeptide antibiotics

**UNIT III.**

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

**UNIT IV.**

- Chemotherapy of fungal and viral diseases
- Chemotherapy of protozoal diseases and helminth infections

**R15****UNITV. Principles of toxicology & Principles of bioassays.**

- a. Definition of poison, general principles of treatment of poisoning
- b. Treatment of barbiturate, opiod, organophosphorous and atropine poisoning.  
Heavy metals and heavy metal antagonisits. LD<sub>50</sub>, ED<sub>50</sub> and therapeutic index
- c. Principles of bioassays and errors in bioassys.
- d. Study of bioassay methods for the following drugs
  - i. Digitalis ii. d-tubocurarine, iii. Oxytocin iv. Insulin v. HCV

**Text Books:**

1. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4<sup>th</sup> Ed.
2. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann, 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.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>CLINICAL AND HOSPITAL PHARMACY</b>	<b>Code</b>	<b>15R00703</b>
<b>CourseYear</b>	<b>B.Pharmacy IV year</b>	<b>Sem</b>	<b>I</b>
<b>Theory</b>	<b>3hrs/week</b>	<b>Tutorial</b>	<b>1hr/week</b>
<b>End exam</b>	<b>70 Marks</b>	<b>Internal exam</b>	<b>30Marks</b>
<b>Credits</b>	<b>3</b>		

**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,

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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. A Textbook of clinical pharmacy practice: Essential concepts and skills, Dr G Parthasarathy et al. Orient Longman Pvt Ltd. ISBN: 8125026
- b. Leon Shargel, Comprehensive pharmacy review, Latest Edition
- c. Health Education and Community Pharmacy, Gupta AK, CBS, Publ. and Distributors New Delhi – (2010).

**Reference Books:**

1. J.G. Hardman and Lee E. Limbard, Goodman & Gilman, The Pharmacological basis of therapeutics, McGraw-Hill, Health Professions Divn.
2. Health Education and Community Pharmacy, NK Jain, CBS, Publ. and Distributors New Delhi.
3. *Hospital pharmacy* by Hassan.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>MEDICINAL CHEMISTRY-II</b>	<b>Code</b>	<b>15R00704</b>
<b>CourseYear</b>	<b>B.Pharmacy IV year</b>	<b>Sem</b>	<b>I</b>
<b>Theory</b>	<b>3hrs/week</b>	<b>Tutorial</b>	<b>1hr/week</b>
<b>End exam</b>	<b>70 Marks</b>	<b>Internal exam</b>	<b>30Marks</b>
<b>Credits</b>	<b>3</b>		

**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**

**Drugs acting on renal system Renin-Angiotensin system inhibitors:** Captopril\*, Enalapril\*, Losartan\*.

**Diuretics:** Acetazolamide, Hydrochlorthiazide\*, Furosemide\*, Ethacrynic acid\*, Spironolactone, Amiloride, Triamterene and Mannitol. SAR- Carbonic anhydrase inhibitors, Thiazides, Loop diuretics.

**UNIT II**

**Drugs acting on CVS**

**Anti anginal agents & vasodilators:** Nitroglycerin\*, Isosorbide dinitrate\*. Ion channel blockers- Verapamil, Diltiazem, Nifedipine, Amlodipine\*.

**Antithrombotic agents-** Aspirin, Dipyridamole, Clopidogrel\*

**Antiarrhythmic drugs:** Quinidine, Procainamide\*, Lidocaine, Mexiletine\*, Amiodarone, Sotalol.

**Antihypertensive agents:** classification, Reserpine, Prazosin, Clonidine, Hydralazine, Sildenafil citrate, Minoxidil, Amrinone,. SAR- beta-blockers.



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**Antihyperlipidemic agents:** Fenofibrate\*, Dextrothyroxine, Colestipol, Nicotinic acid,  $\beta$ -Sitosterol, Probucol, Ezetimibe, Simvastatin, Atorvastatin, Rosuvastatin. SAR-HMG CO-A inhibitors

### UNIT III

**Drugs acting on Blood, hypoglycemic agents and thyroid.**

**Anticoagulants:** Factors, Warfarin sodium\*, Dicumarol

**Synthetic hypoglycemic agents:** Tolbutamide\*, Tolazamide, Glipizide, Glimepiride, Gliclazide, Pioglitazone, Metformin\*, Miglitol.

**Thyroid and antithyroid drugs:** Levothyroxine, Liothyronine, Propylthiouracil.

### UNIT IV

**Analgesic, antipyretic and anti-inflammatory agents**

**Opioids:** Morphine, Levorphanol, Pentazocine, Meperidine\*, Methadone, Tramadol\*, Buprenorphine. Opioid antagonist: Naltrexone, Naloxane, Methylnaltrexone.

**NSAIDs:** A note on prostaglandins and leukotrienes. Aspirin, Indomethacin, Sulindac\*, Ketorolac, Ibuprofen, Naproxen, Mefenamic acid, Diclofenac\*, Piroxicam, Celecoxib, Paracetamol\*.

**Management of Gout and Hyperuricemia:** Allopurinol\*, Sulfapyrazole.

**Antimigraine drugs:** Sumatriptan, SAR – Salicylates, Aryl propionic acids.

### UNIT V

**Antibiotics  $\beta$ - Lactams:** Penicillin G, Ampicillin\*, Amoxicillin.  $\beta$ - Lactamase inhibitors: Clavulanate potassium, Sulbactam.

**Cephalosporins:** Cephalexin\*, Cefixime. SAR-Penicillins and Cephalosporin

**Aminoglycosides and Tetracyclines:** Streptomycin, Gentamicin, Tobramycin, Tetracycline, Doxycycline. SAR- Aminoglycosides and tetracyclines

**Macrolides and Lincomycins:** Erythromycin, Azithromycin, Clindamycin.

**Miscellaneous:** Chloramphenicol,

**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 V.

### Text Books

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.
2. An Introduction to Medicinal Chemistry by Graham. L. Patrick, Oxford University publishers.

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3. JH Block & JM Beale (Eds), Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcolt, Raven, Philadelphia, 2004
4. Rama Rao Nadendla, Medicinal Chemistry; Mc Millan Publishers.

**Reference Books:**

1. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, Oxford
2. Abraham (Ed), Burger Medicinal chemistry and 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: I. Oxford University Press, Delhi.
4. Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998. 5. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J. Wiley N.Y.

**R15**
**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>CHEMISTRY OF NATURAL PRODUCTS (CBCC-II)</b>	<b>Code</b>	<b>15R00705</b>
<b>Courseyear</b>	<b>B. Pharm IV year</b>	<b>Semester</b>	<b>I</b>
<b>Theory</b>	<b>3 hrs/week</b>	<b>Tutorial</b>	<b>1hr/week</b>
<b>End exam</b>	<b>70 marks</b>	<b>Internal exam</b>	<b>30 marks</b>
<b>Credits</b>	<b>3</b>		

**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**

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

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

**Cosmeceuticals:**

General introduction to cosmeceuticals, role of herbs in cosmetics. Study of the following cosmeceuticals-Amla, Henna, Cyperus, Soap Nut, Aloe Vera, Turmeric, Sandal Wood and Bitter Orange Peel.

**Neutraceuticals:** Definition, introduction and study of Garlic, Spirulina, Soya and Royal jelly.

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

**UNIT II**
**General structural elucidation of natural products**

Chemical methods for determination of active hydrogen, methoxy, hydroxyl, N-methyl and degradation (Hoffmann, Edman etc) techniques for the determination of ring size. Structural elucidation of Ephedrine, Atropine, Morphine, Papaverine.

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### UNIT III

#### 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, Dioxylone. 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 IV

#### Terpenes & Terpenoids:

Introduction to Volatile oils, terpene vs terpenoids, Classification, isoprene, special isoprene and gem-dialkyl rules. Sources and structures, general extraction procedure for Citral, citral-a (Geranial), citral-b (Neral). Alpha-terpineol, Carvone, Menthol, Menthone, 1,8-Cineole, Camphor. Chemical transformation and interconversion of citral to citronellal, citronellol, geraniol, nerol, geranic acid, p-cymene, alpha-terpeneol and ionones. Conversion and interconversion of camphor into camphoric acid, camphoronic acids, p-cymene, Borneol, isoborneol.

### UNIT V

**Steroids:** Introduction, nomenclature and classification of steroids. Stereochemistry of Cholesterol. Uses of Bile acids, steroidal hormones. Different Sources of steroidal drugs like diosgenin, cholesterol, stigmasterol and ergosterol.

**Synthetic oestrogens** like diethylstilbesterol, hexoesterol, 17-alpha ethinyloestradiol, Interconversions of Estrone, Estrinol, Estradiol. Chemistry of keto and nonketo adrenocorticoids. Anabolic steroids (Structures and uses).

**Cardiac glycosides:** Structures of glycosides from Digitalis, Strophanthus, Squill and Bufa. Enzymatic and acid hydrolytic reactions of the glycosides.

~~Mechanism of action, SAR, therapeutic uses and toxicity.~~

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**R15****TextBooks:**

1. IL Finar, Organicchemistry, Vol. 1 &2, the Englishlanguagebooksociety, London, NewDelhi.
2. O.P. Agarwal, Naturalproductsby. Vol.1 &2, Goelpublications– Meerut.
3. Kokate CK, PurohitA.P. &Gokhale;PharmacognosyNiraliPrakashan, New Delhi.

**ReferenceBooks:**

1. RTMorrison and R.NBoyd, Organic chemistry, AllynandBacon,inc., boston
2. Me–Wolf,ed., Burger”smedicinalchemistry,J. Wiley&sons, NY.
3. F.G. Mann &B. Saunders,PracticalOrganicchemistryLongmansgreen&Co. Ltd., UK.

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**R15**
**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>COMPUTER AIDED DRUG DESIGN (CBCC- II)</b>	<b>Code</b>	<b>15R00706</b>
<b>CourseYear</b>	<b>B.Pharmacy IV year</b>	<b>Sem</b>	<b>I</b>
<b>Theory</b>	<b>3hrs/week</b>	<b>Tutorial</b>	<b>1hr/week</b>
<b>End exam</b>	<b>70 Marks</b>	<b>Internal exam</b>	<b>30Marks</b>
<b>Credits</b>	<b>3</b>		

**Objectives:**

1. CADD course covers the key areas of computational chemistry methods as applied to the modelling of biological processes and to rational drug design, building on students' knowledge of theoretical chemistry.
2. This course also deals with cheminformatics, relations between thermodynamic properties and protein-ligand binding by structure.

**Outcomes:**

1. Describe the use of lead candidates and database representations
2. Explain the drug development pipeline and understand where computational chemistry fits in chemistry
3. Apply how to use software in structure prediction, ligand design methods, docking programs etc.,

**UNITI**

**Introduction to computer aided drug design:** Introduction, types of enzyme inhibition, how drugs are discovered, and the basics of mechanistic drug design, important techniques

**UNITII**  
**Uses of computer graphics in computer aided drug design:** Computer graphics displays, Computed molecular models, Molecular modeling systems for drug design, uses of computer-assisted drug design, extending molecular modeling.

**UNITIII**

**Molecular mechanics and molecular dynamics:** Potential energy function, Non-bonded energy terms, electrostatic energy, hydrogen bonds, energy minimization, applications of theoretical techniques to drug design.

**UNITIV**
**Computer-Aided Drug Design**

**EARLY METHODS:** Statistical Prediction of Pharmacological Activity, Molecular descriptors based on lipophilicity (Partition coefficient 'logP', substituent hydrophobicity

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constant ' $\pi$ '), polarizability (Molar refractivity, Molar volume), steric (Taft's Steric Factor 'Es', Charton's steric parameter  $r_v$ , Verloop parameters), electrostatics (Hammett substitution constant ' $\sigma$ ', ionization 'pKa') and quantum mechanical (Partial atomic charges, dipole moment, HOMO/LUMO)

NEWER METHODS: Forces Involved with Drug-Receptor Interactions, Optical Isomerism and Biological Activity, conformational analysis, Comparative/Homology modeling, Molecular Docking, Pharmacophore modeling, Quantitative Structure-Activity Relationships, Structural alerts, Database Searching and Mining, Isosterism.

### UNIT V

**Inhibitors of Dihydrofolate Reductase:** The enzyme, enzyme – inhibitor interactions, inhibitor design. **Approaches to antiviral drug design:** Rhinovirus as a drug receptor, Designing Antiviral drugs. **Conformational Biological activity relationships for Receptor-selective, conformationally constrained Opioid peptides:** Design of conformationally constrained Delta and  $\mu$  Opioid Receptor-selective peptides, Problems and prospects for rational design of Receptor-selective peptides.

### Text Books:

1. **Computer aided drug design** Methods and Applications by Thomas J. Perun, C.L. Propst; Marcel Dekker, 2010.
2. Wilson and Gisvold's **Text book of Organic Medical and Pharmaceutical Chemistry** by John M. Beale, John H. Block; Lippincott Williams & Wilkins, 12<sup>th</sup> Edition, 2011.
3. **Molecular Modelling: Principles and Applications** by Andrew R. Leach, Published by Pearson Education EMA, January 2001.

**R15**
**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

Subject	PHARMACOVIGILANCE (CBCC- II)	Code	15R00707
CourseYear	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)



**R15****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, 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, 2<sup>nd</sup> edition.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>NOVEL DRUG DELIVERY SYSTEMS LABORATORY</b>	<b>Code</b>	<b>15R00708</b>
<b>Course year</b>	<b>B. Pharm IV year</b>	<b>Semester</b>	<b>I</b>
<b>Lab</b>	<b>4 hrs/week</b>	<b>Tutorial</b>	<b>NIL</b>
<b>End exam</b>	<b>70 marks</b>	<b>Internal exam</b>	<b>30 marks</b>
<b>Credits</b>	<b>2</b>		

**Scope:** This subject will provide an opportunity for the student to learn about preparation and evaluation of Novel Drug Delivery Systems.

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

- Understand various Novel Drug delivery systems and their preparations.
- Provide knowledge on filing of various regulatory agencies.

**Outcomes:**

- Acquire skill in preparation and evaluation of various Novel formulations.
- Acquire the knowledge of Product development and filing to various regulatory agencies.

**I. EXPERIMENTS:**

- Preparation and evaluation of Matrix Tablets
- Preparation and evaluation of Transdermal Drug Delivery Systems.
- Formulation and evaluation of Mucoadhesive Delivery Systems.
- Evaluation of Market Sustained Release Formulations.
- Preparation and evaluation of microspheres.
- Assignment on Product development and filing to various regulatory agencies, FDA, TGA. Etc (Ref.: [www.fda.gov](http://www.fda.gov))

**II. Demo/ Workshop**

Floating drug delivery system.

**III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION**

Advances in novel drug delivery.

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**R15****Text Books:**

1. N.K. Jain, Advances in Control & Novel drug delivery, CBS Publishers.
2. NK Jain, Pharmaceutical product development, CBS publishers.
3. L. Lachman, H.A. Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy by, Lea &Febieger, Philadelphia Latest Edn.

**Reference Books:**

1. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVthed, marcel dekker,usa, 2005.
2. Controlled drug delivery systems by Robinson.
3. YiewChien, novel drug delivery systems, 2<sup>nd</sup>ed, marcel dekker 2003.

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**R15****JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>CLINICAL AND HOSPITAL PHARMACY LABORATORY</b>	<b>Code</b>	<b>15R00709</b>
<b>Course year</b>	<b>B. Pharm IV year</b>	<b>Semester</b>	<b>I</b>
<b>Lab</b>	<b>4 hrs/week</b>	<b>Tutorial</b>	<b>NIL</b>
<b>End exam</b>	<b>70 marks</b>	<b>Internal exam</b>	<b>30 marks</b>
<b>Credits</b>	<b>2</b>		

**Scope:** This subject will provide an opportunity for the student to learn about various parental preparations.

**Objectives:** Upon completion of the subject student shall be able to Underst and various Sterilization techniques and parenteral preparations. Provide knowledge on Role of Pharmacist in patient counseling.

**Outcomes:**

1. Acquire skill in preparation parenteral Preparations.
2. Acquire the knowledge on First Aid treatment and improving patient Compliance.

**I. EXPERIMENTS:**

1. Preparation of water for injection IP
2. Test for pyrogens on water for injection IP
3. Determination of suitability of NaCl for preparation of transfusion fluid by flame photometer
4. Hydrolytic resistance test on glass used for transfusion fluids
5. Preparation of 5% W/V dextrose IV infusion IP
6. Preparation of 0.9% W/V NaCl IV infusion IP
7. Preparation of Compound NaCl injection (Ringers solution) IP
8. Preparation of NaCl& dextrose injection IP
9. Preparation of sodium bicarbonate intravenous infusion BP
10. Determination of sinking time and water holding capacity of absorbent cotton wool IP
11. Demonstration: Sterilization of surgical instruments, syringes, needles, rubber gloves, hospital fabrics and surgical dressings

**II. ASSIGNMENT**

1. Assignment 1: Study of role of pharmacist in first aid treatment
2. Assignment 2: Study of role of pharmacist in improving patient compliance

**R15**
**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**

<b>Subject</b>	<b>MEDICINAL CHEMISTRY-II LABORATORY</b>	<b>Code</b>	<b>15R00710</b>
<b>Course Year</b>	<b>B.Pharmacy IV year</b>	<b>Sem</b>	<b>I</b>
<b>Lab</b>	<b>4hrs/week</b>	<b>Tutorial</b>	<b>NIL</b>
<b>End exam</b>	<b>70 Marks</b>	<b>Internal exam</b>	<b>30 Marks</b>
<b>Credits</b>	<b>2</b>		

**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

- c. Synthesis various chemical compounds.
- d. 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.

**EXPERIMENTS:**

1. Synthesis of Paracetamol from p-amino phenol
2. Synthesis of Cinnamic acid from benzaldehyde
3. Synthesis of Benzotriazole from o-phenylene diamine
4. Synthesis of 1-phenyl-3-methyl-5-pyrazolone from hydrazine hydrate
5. Synthesis of 7-Hydroxy-4-methyl coumarin from resorcinol and ethyl acetoacetate
6. Synthesis of Salicylaldehyde from phenol
7. Identification and test for purity for Aspirin tablet as per IP
8. Identification and test for purity for Acetazolamide tablet as per IP
9. Identification and test for purity for propranolol tablet as per IP
10. Identification and test for purity for Diclofenac sodium tablet as per IP
11. Identification and test for purity for Paracetamol tablet as per IP

**II. DEMO/WORKSHOP:** Microwave assisted organic synthesis, Purification of synthesized compounds (Column chromatography), Demo on Thin layer chromatography.

**R15**

**III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION** Antibiotic discovery in the twenty-first century: Current trends and future perspectives, Current Trends in  $\beta$ -Lactam based  $\beta$ -Lactamase inhibitors and CVS agents.

**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.

**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

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