**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR ANANTHAPURAMU**

<table>
<thead>
<tr>
<th>Subject</th>
<th>NOVEL DRUG DELIVERY SYSTEMS</th>
<th>Code</th>
<th>13R00801</th>
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<tr>
<td>Course year</td>
<td>B. Pharm IV year</td>
<td>Semester</td>
<td>II</td>
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<tr>
<td>Theory</td>
<td>3 hrs/week</td>
<td>Tutorial</td>
<td>1hr/week</td>
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<td>End exam</td>
<td>70 marks</td>
<td>Internal exam</td>
<td>30 marks</td>
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<td>Credits</td>
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**UNIT I Fundamentals of Controlled Drug Delivery System:**
- 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 Transdermal Drug Delivery Systems:** Fundamentals, permeation of drugs across the skin, types of TDDS, Materials employed and Evaluation of TDDS.

**Mucoadhesive Delivery Systems:** Mechanism of bioadhesion, mucoadhesive materials, formulation and evaluation of mucoadhesive-based systems.

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

**UNIT V Miscellaneous delivery systems:** Introduction, Principle and applications of Floating drug delivery, colon specific drug delivery and Ocular drug delivery.

**Text Books:**

**Reference Books:**
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
3. E.A Rawlkins, Bentley’s Text Book of Pharmaceutics, Elbs publ
4. HC Ansel, Introduction to Pharmaceutical Dosage forms 3rd Indian Ed; K M Varghese & Co., Bombay
UNIT I
Fermentation Technology: Isolation, Selection, Screening of Industrially important microbes, Strain improvement. Types, design & operation of Bioreactor. Types of fermentations, optimization of fermentation process, Principle and Procedure involving in downstream process and effluent treatment.
Specific Fermentations: Selection of organism, fermentation & purification of antibiotics (penicillin, streptomycin, tetracyclin, and erythromycin), vitamins (riboflavin and cyanocobalamine), lactic acid, alcohol and acetone.

UNIT II
Recombinant DNA Technology: Introduction to r-DNA technology and genetic engineering, steps involved in isolation of enzymes, vectors, recombination and cloning of genes. Production of bio technology derived therapeutic proteins like humulin, humatrop, activase, intron a, monoclonal antibodies by hybridoma technique, recombivax HB (hepatitis b). Stem cells and their applications.

UNIT III
Immunology & Immunological Preparations: Principles of Immunity, Humoral immunity, cell mediated immunity, antigen – antiboby reactions, hypersensitivity and its applications.
Active & passive immunizations vaccine preparation, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoid, immuno serum & diagnostic agents.

UNIT IV
Enzyme Technology: Techniques of immobilization of enzymes, factors affecting enzyme kinetics, advantages of immobilization over isolated enzymes. Study of enzymes such as hyaluronidase, penicillinase, streptokinase, streptodornase, amylase, protease etc. immobilization of bacteria & plant cells.

UNIT V
Introductory study & applications of bioinformatics, proteomics and genomics, Nanobiotechnology, Gene therapy.

Text Books:
1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ- Panima publication co-operation, New Delhi.

Reference Books:
2. K. Kielschlicb “Biotechnology” Vol 6, Verlegchemie, Switzerland.
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.
Smooth muscle relaxants: Papaverine and related compounds like ethaverine, Dioxyline. Structures and uses of these compounds.
Ergot alkaloids: Classification, structures, hydrolytic products, pharmacological actions, therapeutic uses and toxicity. Synthetic derivatives: Methyl ergonovine (Methyl ergometrine), LSD, Ethysergide.

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

UNIT IV
Steroids:
steroids (Structure and uses). **Cardiac glycosides:** structures of glycosides from Digitalis, Strophanthus, Squill and Buca. 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) J B Harborne, Phyto Chemical methods. Springer.

**Reference Books:**
1. RT Morrison and R.N Boyd, Organic chemistry, Allyn and Bacon, inc., boston
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 pharmacognocy, CBS Publ.
UNIT I
Basics of Statistics:
Types of data, Collection of data, Variables and variation, sample, population, statistic and parameter, Measures of central tendency, Measures of Dispersion, Coefficient of variation, Graphical representation of data: Histogram, Semilogarithmic plots, bar, pie diagrams, binomial, Poison and Normal distributions, kurtosis and skewness.

UNIT II
Correlation and Regression:
Correlation, Spearman coefficient of correlation, Pearson’s rank correlation, Regression analysis, linear regression
Statistical Inference: Basics of testing hypothesis: Null Hypothesis, Alternate Hypothesis, Level of Significance, Confidence interval, Standard errors, parametric and non-parametric tests used in pharmaceutical experiments

UNIT III
ANOVA:
one way and two way analysis, CRD, RBD, Latin square designs, SQC, Applications of statistical concepts in pharmaceutical sciences

UNIT IV
Introduction to Computers:
Components of computers, computer languages, use of computers, Introduction to operating system.
MS-OFFICE: MS-WORD, MS-EXCEL, MS-POWERPOINT. Information technology: Internet and world wide web, Search strategies.

UNIT V
Computer applications in pharmaceutical and clinical studies, computer validation - introduction
Work Study - Basic procedure involved in method study and work Measurement-Statistical Quality Control: \( \bar{X} \) chart, R chart, c chart, p chart, (simple Problems), Acceptance Sampling, Deming’s contribution to quality.

Text Books:
5. RonMansfiled, Working in Microsoft office.
6. Text book of Statistical Methods and Computer applications by Dr. Ramakrishna Prasad.
UNIT I  Introduction to clinical pharmacy:
  a. Prospects and perspectives of clinical pharmacy in national and international scenario, scope of clinical pharmacy
  b. Therapeutic Drug Monitoring.
  c. Clinical Pharmacokinetics and individualization of Drug Therapy.
  d. Concept of Essential Drugs and Rational Drug use.

UNIT II  Introduction to daily activities of Clinical pharmacist
  a. Drug therapy monitoring (Medication chart review)
  b. Adverse Drug Reactions & Drug Interactions
  c. Patient counseling
  d. Drug and poison information.
  e. Ward round participation.

UNIT III  Clinical laboratory tests and interpretation of test results.
  a. Hematological (complete blood picture)
  b. Pulmonary function tests
  c. Tests associated with cardiac disorders
  d. 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

Text Books:

Reference Books:
2. Health Education and Community Pharmacy, NK Jain, CBS, Publ. and Distributors New Delhi.
3. Hospital pharmacy by Hassan.
I. EXPERIMENTS:
1. Preparation and evaluation of Matrix Tablets
2. Formulation and evaluation of Film Coated Tablets.
3. Formulation and evaluation of Enteric Coated Tablets.
5. Formulation and evaluation of Mucoadhesive Delivery Systems.
7. Preparation and evaluation of microspheres.

II. Demo/Workshop
Floating drug delivery system.

III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION
Advances in novel drug delivery.

Text Books:
2. NK Jain, Pharmaceutical product development, CBS publishers.

Reference Books:
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
3. E.A Rawlkins, Bentley’s Text Book of Pharmaceutics, Elbs publ
4. HC Ansel, Introduction to Pharmaceutical Dosage forms 3rd Indian Ed; K M Varghese & Co., Bombay
7. Controlled drug delivery systems by Robinson.
I. **EXPERIMENTS:**
1. Isolation of antibiotic producing microorganism from soil.
2. Enzyme immobilization by Ca-alginate method.
3. Determination of minimum inhibitory concentration of the given antibiotic.
4. Standardization of Cultures.
5. Microbiological assay of Antibiotics / Vitamins.
6. Production of alcohol by fermentation techniques.
7. Comparison of efficacy of immobilized cells.
8. Isolation of mutants by gradient plate technique.
10. Preparation of blood products / Human normal immunoglobulin injection
11. Extraction of DNA and RNA and their estimations by colorimetry.

II. **DEMO/WORKSHOP:**
Production of Antibiotics by Fermentation, Development of a Simple Biosensor.

III. **ASSIGNEMENT/SEMINAR/GROUP DISCUSSION:**
Monoclonal antibodies and Diagnosis, New Drug Targets and Vaccine Development, Stem cells and their applications.

**LIST OF MINIMUM EQUIPMENTS REQUIRED**
1. Micropipettes
2. Eppendorf’s tubes
3. Ultra centrifuge
4. Dessicators
5. Gel electrophoresis unit
6. Small scale bioreactor
7. Syringes
8. laminar flow bench
9. Autoclave
10. Hot air oven
11. BOD incubator
12. Rotary shaker
13. Anerobic jar
14. Colorimeter
15. Adequate glassware
S.No  | Name of the experiment                                                                                                                                                                                                 | References:                                                                                                                                                                                                 | LIST OF MINIMUM EQUIPMENTS REQUIRED                                                                 |
---    |------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
1      | Preparation of different alkaloidal reagents, like Dragendroff, Mayer, Wagner’s, Hager’s etc and testing of some alkaloids and plant extracts using these reagents. Identification of alkaloids by specific colour tests. | 1. Practical Pharmacognosy, CK Kokate, Nirali Prakashan  
2. Practical Pharmacognosy, Khandelwal, Nirali Prakashan  
3. Practical Pharmacognosy Iyengar, Manipal Press Ltd.  
5. Indian Pharmacopoeia. 1966.  
7. Herbal Pharmacopoeia, IDMA, India.                                                                                                                                 | 1. Soxhlet extraction apparatus  
2. Heating mantle  
3. Steam distillation apparatus  
4. TLC kit  
5. Water bath  
6. Hot plates  
7. Oven  

References:
1. Practical Pharmacognosy, CK Kokate, Nirali Prakashan  
2. Practical Pharmacognosy, Khandelwal, Nirali Prakashan  
3. Practical Pharmacognosy Iyengar, Manipal Press Ltd.  
5. Indian Pharmacopoeia. 1966.  
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<td>3 hrs/week</td>
<td>NIL</td>
<td>50 marks</td>
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| credits | 2 |

### I. Experiments
1. Computation of Mean, S.D and Co-efficient of variation
2. Computation of Correlation
3. Equations of Regression lines
4. Fitting a Straight line
5. Student t-test
6. Chi-square test
7. ANOVA-oneway
8. ANOVA-two way
9. CRD Experimentation
10. Randomised Block Design
11. Latin Square Design
12. Construction of x-chart
13. Construction of R-chart
14. MS-WORD Experiment
15. MS-excel and Powerpoint

### II. Seminar/Group discussion/Assignment:
1. Applications of statistics in pharmaceutical computations
2. Computer applications in pharmaceutical and clinical studies

### References: