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SUBJECT: Pharmaceutical Biotechnology
SUBJECT CODE: B501T
RATIONALE: Biotechnology has become an important technology for obtaining drugs from bio-sources. Large numbers of drugs are prepared using biotechnology. The course enables student to learn basic technology for production of various classes of drugs.

COURSE OBJECTIVES:
To learn the basic principles of technology involved in production of bio-derived drugs

LEARNING OUTCOMES: The student should be able to:
1. Describe the basic principles underlying the technology used for production of drugs using biotechnology.
2. Describe the methods used in the production of various vaccines, antibiotics and other biological products.

PREREQUISITES: General biology, Anatomy, Physiology, biochemistry

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CONTENT:

1. **Immunology and Immunological Preparation:**
   Principles, antigens and haptens, immune system cellular humoral immunity, immunological tolerance, antigen antibody reaction and their application. Hypersensitivity, Active and Passive immunization; Classification of immunological preparations, Vaccines, Sera, Toxoids— General methods of preparation, standardization and storage. Brief introduction of venums. 15

2. **Immunologicals**
   MMR Vaccine, Rubella Vaccine, Polio Vaccine, Pneumonia Vaccine, Diphtheria Vaccine, BCG Vaccine, Chicken pox Vaccine, Influenza Vaccine, Anti-RH factor, Hepatitis B Typhoid, Anti rabies serum, and Tetanus serum, Anti snake vaccine. 20

3. **Biopharmaceuticals:** Definition, Classification and applications. 05

4. **Genetic Recombination:**
   Microbial genetics and variation. Introduction of DNA, Mutation and its applications, Methods of genetic modification and its applications in industrial microbiology. 15

5. **Antibiotics:**
   Historical development of antibiotics, antimicrobial spectrum and methods used for their standardization. Screening of soil for organisms producing antibiotics, fermenter, its design, and control of different parameters. Isolation of mutants, factor influencing rate of mutation. Design of fermentation process. Isolation of fermentation products with special reference to penicillin, streptomycins, tetracyclines and vitaminB12. 15

6. **Microbial Transformation:**
   Introduction, types of reactions mediated by microorganisms, design of biotransformation process, selection of organisms, biotransformation process and its improvements with special reference to steroids. 15
Enzyme immobilization:
Technique of immobilization, factors affecting enzyme kinetics. Study of enzymes such as hyaluronidase, penicillinase, streptokinase and streptodornase, amylase and proteases etc. Immobilization of bacteria and Plant cell.

BOOKS RECOMMENDED:

1. "Pharmaceutical Biotechnology", Purohit S S, Ab Grobias Publication
2. "Pharmaceutical Biotechnology", Sambhamurthy K., New Age International Publication
4. "Biotechnology”, Singh B.D., Kalyani Publication
5. "Biotechnology Unlipfed”, Gracs Eric S., University Press Elsevier
7. "Methods In Biotechnology And Bioengineering” Vyas S.P., Cbs Publication
SUBJECT: Pharmaceutical Biostatistics
SUBJECT CODE: B502T & B502P
RATIONALE: Biostatistics is used in day to day life of any professional. The course enables student to learn the fundamentals of biostatistics and its application in pharmacy.

COURSE OBJECTIVES:
1. To learn fundamentals of statistics
2. To learn different methods of statistics for data description and data analysis with special focus on pharmaceutical sciences.

LEARNING OUTCOMES: The student should be able to:
1. Explain the basic principles of statistics.
2. Carry out data analysis using different statistical tools pertaining to data variability, probability and correlation.
3. Carry out correct sampling for collecting data.

PREREQUISITES: Basic arithmetics

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CONTENT:

1. Basic concepts of Biostatistics-
   Statistics & Biostatistics, Variables and Constants, population and sample
   Statistical data- Classification, Presentation and tabulation of data, Frequency distribution-
   graphical presentation of data
   10

2. Central tendency- Central tendency and its measures with their properties, comparisons of
   different measures, Applications in pharmaceutical studies
   10

3. Variability- Dispersion of data, its measures, properties of different measures, coefficient of
   variation, Measures relating to the shape of the distribution graph- Skewness and Kurtosis
   10

4. Probability distributions- Binomial distribution, Poisson Distribution, Normal
   Distribution- Applications in pharmacy
   15

5. Correlation & Regression
   Correlation- Definition, Types, Methods of analysis- Scatter diagram, correlation coefficient,
   spearman’s correlation
   10

6. Tests of significance-
   Terms and Procedure of testing of hypothesis, Tests of significance for large samples, Tests
   of significance for small samples- t-distribution, and its applications in testing of hypothesis,
   F-distribution and its applications
   15

   a. t-test- t2-distribution, properties and conditions of t2- distribution, Applications of t2-
   distribution in testing of hypothesis
   10

   b. ANOVA- Definition, Technique and assumptions, One-way and Two-way ANOVA -
   Applications of mathematical modeling
   10

   c. Sampling Methods: Sample and population, need of sampling, sample size, methods of
   sampling
   10
B502P Pharmaceutical Biostatistics Practical

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<tr>
<td>1</td>
<td>(Use of functions and data analysis component of Excel)</td>
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<td>2</td>
<td>Finding average and variability</td>
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<td>Performing various significance tests</td>
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<td>Various exercises based upon use of computers in treatment of Pharmacokinetic data and BA –BE Data.</td>
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<td>Demonstration of Biostatistics softwares and its application in pharmacy</td>
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<td>6</td>
<td>Linear regression and correlation analysis</td>
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BOOKS RECOMMENDED:

1. “Methods Of Biostatistics”, Mahajan
6. “Probability And Statistics”, Mary R. Spiegel
7. Biostatistics and computer applications- Shah
8. Fundamentals of Biostatistics - Khan and Khanum
10. Biostatistical Methods - Looney
SUBJECT : Pharmacognosy -III
SUBJECT CODE : B503T & B503P
RATIONALE : It provides knowledge of drugs of natural origin. Since ages humans have been using drugs from natural origin. Many of the allopathic drugs also have herbal origin. Learning these drugs is of great value for pharmacy professionals as these drugs have important place in treatment of diseases.

COURSE OBJECTIVES :
1. To learn general morphological and microscopical characters of crude drugs
2. To understand general methods of checking purity of herbal drugs.

LEARNING OUTCOMES: The student should be able to:
1. Identify the crude drugs belonging to different classes based on morphological, microscopical and chemical properties.
2. Narrate the therapeutic and pharmaceutical uses of these drugs

PREREQUISITES: Biology and Pharmacognosy-I of semester-III and IV

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CONTENT:


2. Study of traditional drugs: I Adusa, Apamarg, Bhilawa, Chakramadu, Chitrak, Gokhru, Satavari, Gymnema, Kalijiri, Karanj, Long Pepper, Malkagni, Manjith, Methi. 40

3. Tannin: Definition, classification & chemical tests of tannins; Catechu, Gall, Myrobalan 20

B503P Pharmacognosy-III Practical

To study morphology and microscopy of following:
1. Senna leaf,
2. Thevatia leaf, Chitrak root
3. Satavari root,
4. Liquorice,
5. Karanj Seed
6. Long pepper fruit
7. Adusa leaf,
8. Apamarg herb

CONTENT:
9. Arjuna bark, Quassia wood
10. Chakramadu Leaf
11. Gymnema leaf
12. Majith root
13. To study morphology of Ginseng, Dioscorea, Gokhru, Digitalis, Squill, Strophanthus.
14. To study morphology of Arjuna, Aloe, Senna, Rhubarb, Cascara, Psoralea, Ammi Majus.
15. To study morphology of Ammi Visnaga, Gentian, Saffron, Chirata, Quassia.

BOOKS RECOMMENDED:

1. Sims, Medicinal Plant Glycosides, University Of Toronto Press.
3. Ashutosh Kar, Pharmacognosy And Pharmacobiotechnology, New Age International
5. Rangari & Rangari, Text Book Of Pharmacognosy
6. Kokate C.K. Practical Pharmacognosy, Vallabh Prakashan, Delhi
7. Kokate C.K, Purohit A.P. And Gokhale S.B. Pharmacognosy (Degree) Nirali Prakashan,
12. Tyler V.C., Brady L.R. And Robers W.E. , Pharmacognosy, Lea And Febiger, Ph
14. Ayurvedic Pharmacopoeia Of India
15. Herbal Pharmacopoeia 1-2 (IDMA)
17. The Wealth Of India – First Supplement Series ( Row Materials ) Vol- 1to 10
18. Who Monographs On Selected Medicinal Plants Vol-1-2
19. Indian Medicinal Plants (Plate) Vol-1-4, Kirtikar K. R
20. Indian Medicinal Plants (Text) Vol-1-4, Kirtikar K. R.
21. Quality standards of Indian medicinal plants vol I-IV(ICMR)
22. MG Chauhan, Microscopy Of Bark Drug, Jamnanagar Ayurved University
23. MG Chauhan, Microscopy Of Leaf Drug, Jamnanagar Ayurved University
SUBJECT: Pharmacology-III
SUBJECT CODE: B504T & B504P
RATIONALE: This is one of the core subjects of Pharmacy field where student learns the biological effects of drugs. The subject has direct application to the profession as it teaches the student about how the drug produce effect, what effects are produced, what side effects are produced, where and when it should be used etc. The subject is an extension of Pharmacology-I learnt in Semester-III

COURSE OBJECTIVES: To learn the mechanism of action, pharmacological effects, pharmacokinetics, adverse effects, therapeutic application of various classes of drugs with special attention to drugs acting on cardiovascular, urinary, gastrointestinal system.

LEARNING OUTCOMES: The student should be able to:
1. Narrate the principles involved in measurement of drug effects
2. Classify the drugs according to pharmacological classes
3. Explain the mechanism of action, pharmacodynamics and pharmacokinetic effects of drugs, adverse effects, contraindications and therapeutic application of various classes of drugs.
4. Conduct some simple in vivo experiments to demonstrate the pharmacological actions of the drugs.

PREREQUISITES: Knowledge of Human Anatomy Physiology, Health Education, Biochemistry and basic physics and chemistry. Fundamentals of pharmacology learnt in previous semesters.

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CONTENT:
1. Pharmacology of Nitric oxide, endothelins, Atrial Natriuratic Peptide (ANP) & purines: 10
2. Pathophysiology of and Drugs used in: Congestive Cardiac Failure, Angina, Myocardial Infarction, Cardiac Arrhythmias, Hypertension, Hyperlipidemia and Atherosclerosis, Anemia, Coagulation disorders, Shock: 40
3. Drugs Acting on Urinary System: Fluid and electrolyte balance, Diuretics, Anti diuretics, Urine acidifying and alkalinizing agents: 15
5. Concepts of RIA, Radioligand Studies, ELISA, HTS: 15
B504P  Pharmacology-III Practical

1. Demonstration of the isolated perfused mammalian heart by Langendroff’s technique.
2. To study the effect of various drugs on isolated frog’s heart using simulation software.
3. To study the effect of various drugs on rat/cat/dog blood pressure using simulation software.
4. To study the effect of various drugs on ciliary motility of frog (CAE)
5. To study the antidiarrheal effect of lopamide on castor oil/Carbachol induced diarrhea.
6. To study effect of Aspirin on aggregation & deaggregation of platelets in human plasma.
7. Bioassay of Heparin
8. To evaluate the anti-inflammatory effect of aspirin using carrageenan induced rat paw edema method
9. To study various methods of Bioassay of agonists and antagonists
10. To perform bioassay of Ach/ Histamine using Rat/ Guinea pig ileum by Graphical method
11. To perform bioassay of Ach using Rat ileum by Matching method
12. To perform bioassay of Ach using Rat ileum by 3 point method
13. To perform bioassay of Ach/ Carbachol using Rat ileum by 4 point method
14. To perform bioassay of Atropine/ Pheniramine maleate using Rat / Guinea pig ileum by Graphical method
15. To determine the nature of Unknown drug using Rat ileum.
16. To study the effect of urea, furosemide & Acetazolamide on rat urine output

BOOKS RECOMMENDED:

1. Pharmacological Basis Of Therapeutics By Goodman & Gillman
2. Pharmacology And Pharmacotherapeutics By Satoskar & Bhandarkar
3. Essentials Of Pharmacotherapeutics By F.S.K. Barar
4. Essentials: Of Medical Pharmacology By K.D. Tripathi
5. Pharmacology By Rang & Dale
6. Fundamentals Of Experimental Pharmacology By M.N. Ghosh
8. Exp. P’cology by R.V. Goyal
9. Pharmacological Experiments On Isolated Preparations By Perry
10. Medical Pharmacology By Goth
11. Pharmacology By Gaddum
12. Lewis Pharmacology By Crosland
13. Textbook Of Pharmacology By Bowman & Rand
14. Elements Of Pharmacology By Dr. Derasari & Dr. Gandhi
15. Drug Interactions By Hansten
16. Introduction To General Toxicology By Aries Simonsis & Offermeier
17. Toxicology: The Basic Science Of Poisons By Casorett & Doull
18. Clinical Pharmacology By Lawrence
19. Principles Of Drug Action By Goldstein Aronow & Kalaman
20. Drug Treatment By Avery
SUBJECT : Pharmaceutical Analysis-II
SUBJECT CODE : B505T & B505P
RATIONALE : Measuring Drug purity is a primary requirement to ensure the quality of drugs. Quantifying the purity of compound can be done by different techniques. Some of the most commonly used techniques will be taught in this subject. This will make the student capable to work in a quality control department of the pharmaceutical industry.

COURSE OBJECTIVES :
1. To make student learn about various guidelines for method validation.
2. To provide the hands-on experience by actually conducting these assays in the lab.

LEARNING OUTCOMES: The student should be able to:
1. Narrate the principles of methods and instruments used in assay of various drugs and chemicals.
2. Conduct assays of some drugs using these methods and instruments.
3. Describe basic principles and guidelines pertaining to quality assurance of drugs.

PREREQUISITES:
Basic knowledge of physics, chemistry and pharmaceutical calculations taught in earlier semesters. Also knowledge of Pharmaceutical analysis studied in Semester-II becomes mandatory for this subject.

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CONTENT:

1. Theoretical considerations and application in drug analysis and quality control of the following analytical techniques.
   **Precipitation Titrations**: Precipitation reactions, Solubility products, Effect of acids, temperature and solvent upon the solubility of a precipitate. Argentometric titrations and titrations involving ammonium or potassium thiocyanate, mercuric nitrate, and barium sulphate, Indicator, Gay-Lussac method, Mohr’s method, Volhard’s method and Fajan’s method.

2. **Gravimetric analysis**: Precipitation techniques, Solubility products; The colloidal state, Super saturation co-precipitation, Post-precipitation, Digestional washing of the precipitate, Filtration, Filter papers and crucibles, Ignition, Thermogravimetric curves, Specific examples like barium sulphate, aluminium as aluminium oxide, calcium as calcium oxalate and magnesium as magnesium pyrophosphate, Organic precipitants.

3. Extraction procedures including separation of drugs from excipients


B 505 P  Pharmaceutical Analysis-II Practical

1. To determine %w/v of sodium chloride using Volhard’s method.
2. To determine %w/v of sodium chloride using Mohr’s method using potassium chromate as indicator.
3. To determine %w/v of sodium chloride using Mohr’s method using adsorption indicator.
4. To determine %w/v of iodides by using standard solution of silver nitrate.
5. To determine moisture content of the given sample by Karl Fischer titration.
6. To find out the concentration of given acid solution by potentiometer.
7. To determine the content of sulfamethizole (from tablets) by potentiometer.
8. To find out the concentration of given acid solution by PH meter.
9. To determine the dissociation constant of given acetic acid solution by PH metry.
10. To find out the concentration of given acid solution by using Conductometer.
11. To find out optical activity of dextrose in the given solution of dextrose by using polarimeter.
12. To determine sulphate content as Barium sulphate by gravimetric method.
13. To determine chloride content as Silver chloride by gravimetric method.
14. To determine content of paracetamol and diclofenac sodium from the formulation (tablet).
15. To determine ascorbic acid content from tablets of ascorbic acid.
16. To determine aluminium content from aluminium hydroxide gel.

BOOKS RECOMMENDED:

SUBJECT: Biochemistry-I
SUBJECT CODE: B506T
RATIONALE: Understanding the chemistry of life is fundamentally required for studying the effect of drugs on human body. The course will enable student to learn the basic chemical reactions occurring in the human body. Also the various factors which can regulate this chemical processes will be taught.

COURSE OBJECTIVES:
1. To learn the structure and function of various biochemicals
2. To learn the basic metabolic processes occurring within the human body and factors regulating the same.

LEARNING OUTCOMES:
1. Describe the structure and functions of various biochemicals
2. Describe the various biochemical pathways occurring within the human body.
3. Describe the basic principles of enzymology.
4. Classify the different enzymes.

PREREQUISITES: Physics, chemistry, human anatomy physiology

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CONTENT:

1 Biological macromolecules: carbohydrates
   Introduction to carbohydrates.
   1.1.1 Nomenclature, definition and classification of carbohydrates.
   1.1.2 Monosaccharides.
   Classification, structural aspect and biological significance.
   1.1.3 Disaccharides.
   1.1.4 Oligosaccharides.
   1.1.5 Polysaccharides.
   1.1.5.1 Structure, classification, nomenclature and function.
   1.1.5.2 Storage polysaccharides.
   1.1.5.3 Structural polysaccharides.
   1.1.6 Introduction to glycoprotein’s and proteoglycans.

   20

2 Introduction to lipid
   2.1 Structure and function diversity of lipids.
   2.1.1 Definition and classification.
   2.1.2 Fatty acids, Triacyl glycerols, glycerophospholipids, Sphingolipids, steroids and other biologically important lipids (Terpenes, steroids, cholesterol etc.)

   15

3 Proteins, structure and function
   3.1 General structure of Amino acids.
   3.1.1 Classification of Amino acids.
   3.1.2 Derivative of amino acids.
   3.1.3 Ionization of amino acids.
   3.1.4 Peptide bond link amino acids in proteins.
   3.1.5 Protein purification techniques.

   20
3.1.6 Composition of amino acid in protein and determining sequence of amino acid residue methods.
3.2 Structure of protein.
3.2.1 Types of protein structure.
3.2.2 Primary structure.
3.2.3 Secondary structure.
3.2.4 Tertiary structure.
3.2.5 Quaternary structure.
3.2.6 Stability of protein structure.
3.3 Various other biologically important protein.

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BOOKS RECOMMENDED: