

## PHARMACEUTICAL BIOTECHNOLOGY (MPB)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPB 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY

60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.  
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy  
b. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
c. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 12 Hrs
2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. 12 Hrs

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| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy  | 12<br>Hrs |
| 4 | Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography f) High Performance Liquid chromatography<br>g) Affinity chromatography  | 12<br>Hrs |
| 5 | a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder diffraction technique, Types of crystals and applications of X-ray diffraction. | 12<br>Hrs |

#### REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons.
2. Principles of Instrumental Analysis – Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis– Modern methods – Part B – J W Munson, Volume 11, Marcel Dekker Series

## MICROBIAL AND CELLULAR BIOLOGY (MPB 102T)

### Scope

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

### Objective

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

### THEORY

60Hrs

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| 1. | Microbiology  | 12  |
|    | Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actinomycetes and virus – structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms – examples and applications | Hrs |
| 2  | Molecular Biology: Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. Gene regulation  | 12  |
|    | Gene copy number, transcriptional control and translational control. RNA processing   | Hrs |
|    | Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in strain improvement, gene mapping of plasmids– types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.  |     |

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| 3 | <p>Cell structure and function</p> <p>Cell organelles, cytoskeleton &amp; cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism &amp; its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues.</p> <p>Cell Cycle and Cytoskeleton</p> <p>Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton &amp; cell movements, Intermediate Filaments.</p> <p>Apoptosis and Oncogenes</p> <p>Programmed Cell Death, Tumor cells, carcinogens &amp; repair.</p> <p>Differentiation and Developmental Biology</p> <p>Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.</p> | 12<br>Hrs |
| 4 | <p>Principles of microbial nutrition</p> <p>Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.</p> <p>Growth of animal cells in culture</p> <p>General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In-vitro screening techniques– cytotoxicity, anti-tumor, anti-viral assays.</p>  | 12<br>Hrs |
| 5 | <p>Microbial pathology</p> <p>Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal &amp; viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.</p>   | 12<br>Hrs |

## REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2<sup>nd</sup> edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6<sup>th</sup> edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins– A Waverly company.

## BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB 103T)

### Scope

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

### Objective

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

### THEORY

60 Hrs

#### 1. Introduction to fermentation technology

12

Basic principles of fermentation

Hrs

Study of the design and operation of bioreactor

Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

Types of bioreactor

CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

Computer control of fermentation process

System configuration and application

#### 2 Mass transfer

12

Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co-efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

Hrs

## Rheology

Rheological properties of fermentation system and their importance in bioprocessing.

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| 3 | Scale up of fermentation process<br>Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.<br>Cultivation and immobilized culture system<br>Cultivation system – batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.<br>Introduction to immobilization<br>Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering. | 12<br>Hrs |
| 4 | Scale down of fermentation process<br>Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.<br>Isolation and screening<br>Primary and secondary, maintenance of stockculture, strain improvement for increased yield.   | 12<br>Hrs |
| 5 | Bioprocessing of the industrially important microbial metabolites<br>a) Organic solvents – Alcohol and Glycerol<br>b) Organic acids – Citric acids, Lactic acids,<br>c) Amino acids – Glutamic acids, Lysine, Cyclic AMP and GMP<br>d) Antibiotics – Penicillin, Streptomycin, Griseofulvin,<br>e) Vitamins – B12, Riboflavin and Vitamin C<br>Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids<br>Regulation governing the manufacturing of biological products .   | 12<br>Hrs |

## REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.



## ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB 104T)

### Scope

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

### Objective

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

### THEORY

60 Hrs

#### 1. Enzyme Technology

12

Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

Hrs

#### 2 Genetic Engineering

12

Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast.  
Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences.

Hrs

Gene library and cDNA

Applications of the above technique in the production of,

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| □ Regulatory proteins | - Interferon, Interleukins |
| □ Blood products      | - Erythropoietin           |
| □ Vaccines            | - Hepatitis-B              |
| □ Hormones            | - Insulin                  |

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| 3 | <p>Therapeutic peptides</p> <p>Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.</p> <p>Transgenic animals</p> <p>Production of useful proteins in transgenic animals and gene therapy.</p> <p>Human Genome</p> <p>The human genome project-a brief study, Human chromosome - Structure and classification, chromosomal abnormalities - Syndromes</p>   | 12<br>Hrs |
| 4 | <p>Signal transduction</p> <p>Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.</p> <p>Oncogenes</p> <p>Introduction, definition, various oncogenes and their proteins.</p>                                       | 12<br>Hrs |
| 5 | <p>Microbial Biotransformation</p> <p>Biotransformation for the synthesis of chiral drugs and steroids.</p> <p>Microbial Biodegradation</p> <p>Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring.</p> <p>Biosensors</p> <p>Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.</p> | 12<br>Hrs |

#### REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose

6. Gene transfer and expression protocols–methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I  
(MPB 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS - polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.