

# **COURSE STRUCTURE**

**M. SC. (MICROBIOLOGY)**

Paper No.	Title of the theory paper	Marks	Practical	Marks
Semester I				
Th-I	Biostatistics Computer Applications and Research Methodology	50	P-I	25
Th-II	Bioenergetics and Enzymology	50	P-II	25
Th-III	Bioinstrumentation Techniques and Applications	50	P-III	25
Th-IV	Industrial Food and Dairy Microbiology	50	P-IV	25
Semester II				
Th-V	Recent Trends in Virology.	50	P-V	25
Th-VI	Molecular Immunology.	50	P-VI	25
Th-VII	Microbial Physiology.	50	P-VII	25
Th-VIII	Microbial Diversity and Extremophiles.	50	P-VIII	25
Semester III				
Th-IX	Enzyme Technology	50	P-IX	25
Th-X	Bioprocess Engineering and Technology.	50	P-X	25
Th-XI	Molecular Microbial Genetics.	50	P-XI	25
Th-XII	Environmental Microbial Technology	50	P-XII	25
Semester IV				
Th-XIII	Recombinant DNA Technology	50	P-XIII	25
Th-XIV	Fermentation Technology	50	P-XIV	25
Th-XV	Bioinformatics, Microbial Genomics and Proteomics.	50	P-XV	25
Th-XVI	Pharmaceutical Microbiology	50	P-XVI	25

\* Semester IV Practical (P- XV and XVI) or a research project of 50 marks.

# M.Sc. MICROBIOLOGY SYLLABUS

M.Sc. Microbiology Course of two years is divided into four semesters.

Each semester is of 300 marks.

Each semester (I, II, III) will have four (04) theory papers each of 50 marks and four practical papers each of 25 marks.

Last semester will have four (04) theory papers each of 50 marks and four practical papers each of 25 marks. In the last semester instead of two practical papers research project of 50 marks will be assigned between three students.

## **Semester I**

Paper-Th-I- Biostatistics Computer Applications and Research Methodology

Paper-Th-II-Bioenergetics and Enzymology

Paper-Th-III- Bioinstrumentation Techniques and Applications

Paper-Th-IV- Industrial Food and Dairy Microbiology

Practical papers P-I to P-IV based on four theory papers.

## **Semester II**

Paper-Th-V- Recent Trends in Virology

Paper-Th-VI-Molecular Immunology

Paper-Th-VII-Microbial physiology

Paper-Th-VIII- Microbial Diversity and Extremophiles

Practical papers P-V to P-VIII based on four theory papers.

## **Semester III**

Paper-Th-IX- Enzyme Technology

Paper-Th-X- Bioprocess Engineering and Technology

Paper-Th-XI- Molecular Microbial Genetics

Paper-Th-XII-Environmental Microbial Technology

Practical papers P-IX to P-XII based on four theory papers.

#### **Semester IV**

Paper-Th-XIII- Recombinant DNA Technology

Paper-Th-XIV-Fermentation Technology

Paper-Th-XV- Bioinformatics, Microbial Genomics and Proteomics

Paper-Th-XVI- Pharmaceutical Microbiology

Practical papers P-XIII to P-XVI based on four theory papers or a research project of 50 marks each.

#### **INFRASTRUCTURE, INSTRUMENTAL LIBRARY & OTHER FACILITIES REQUIRED FOR M. Sc. COURSE IN MICROBIOLOGY (for 25 Students INTAKE CAPACITY).**

1. Two laboratories (for Part I and Part II) each measuring at least 1000 Sq. Ft. With sufficient no. of tables and Stools. Lab should be provided with basic Instruments such as autoclave, incubator, oven, pH meter, hot plate, cyclo mixers, water bath shakers, colorimeter, fridge, distillation plant etc.
2. A culture room with a laminar air flow measuring 300 Sq. Ft.
3. An Instrumentation Room with Double door, Air Conditioner, and inverter, power generator for sophisticated Instruments measuring 500 Sq. Ft.
4. Two Lecture halls (for Part I and Part II) with Overhead projector facility and measuring 400 Sq. Ft. with tables and chairs.
5. A media preparation and a store room at least 400 Sq. Ft.
6. A computer in Bioinformatics Laboratory with 4 – 5 computers (P – IV) with printer and internet facility.

## **LIST OF BASIC INSTRUMENTS REQUIRED FOR M. Sc. PRACTICALS**

1. Laminar Air Flow.
2. Compound Microscope
3. Autoclave
4. Incubators
5. Hot Air Oven.
6. BOD Incubators
7. pH Meter
8. Water Bath Incubator Shaker
9. Colorimeter
10. Spectrophotometer
11. Hot Plate.
12. Cyclomixer.
13. Electrophoretic Apparatus
14. Orbital Incubator Shaker
15. High Speed Centrifuge - (10000 RPM)
16. Distillation Apparatus (Single & Double)
17. Refrigerators
18. Paper Chromatography Cabinet
19. Rough Balances
20. Bacterial Filter Assembly
21. General Purpose Centrifuge.
22. Vortex Mixers
23. Magnetic Stirrers
24. UV Cabinet
25. TLC Apparatus
26. Dissolved Oxygen Meter
27. Metler Balances
28. Digital Balances
29. Water Bath Shakers
30. Colony Counter
31. Rotary Shaker
32. Columns for Chromatography
33. Fraction Collector
34. Gas Burners
35. LPG Cylinders
36. Distillation Apparatus.

## **LIST OF SOPHISTICATED INSTRUMENTS REQUIRED FOR PRACTICAL**

1. UV – Vis Spectrophotometer.
2. Gas Chromatography
3. Sonicator

4. High Speed Refrigerated Centrifuge
5. Microprocessor based pH Analyser
6. Horizontal Paper Electrophoresis Unit
7. Vertical Electrophoresis Unit
8. Submarine Electrophoresis Unit
9. Immuno Electrophoresis Apparatus
10. Power Pack With Constant Voltage or Current Adjustment
11. PAGE Electrophoresis Unit
12. DNA Sequencer
13. ELISA Reader
14. PCR (Thermal Cycler)
15. Gel Documentation Unit
16. Semi Dry Transfer Apparatus
17. Deep Freezer (-30°C)
18. Fermenter
19. Atomic Absorption Spectrophotometer
20. COD & BOD Analyser
21. Phase Contrast Microscope
22. Binocular Microscope
23. HPLC
24. Lyophilizer
25. Pentium IV Computer With Printer
26. Micropipette
27. CO<sub>2</sub> Incubator

#### **OTHER REQUIREMENTS**

The department should have required chemicals, DEHYDRATED MEDIA, STAINS, ACIDS, SOLVENTS, FINE CHEMICALS, ENZYMES, ANTI SERA IMMUNODIAGNOSTIC KITS, and SPECIFIC MICROBIAL CULTERS WITH KNOWN GENETIC MARKERS AND GLASSWARES to conduct the prescribed syllabus. Cold room facility is preferred.

#### **LIBRARY FACILITY**

The library should have ample no of prescribed text books, reference books recommended in the prescribed syllabus and the library should also subscribe National and International and Scientific Magazines.

#### **INSTRUCTIONS**

1. M.Sc. Course of Microbiology is divided into four semesters.
2. Each Semester will have four theory papers and four practical papers, except in the IV semester, either there will be four practical papers or two practical papers and a research project equivalent to two practical papers i.e. for 50 marks. The decision to have practical or research project will be the discretion of the

department and will depend upon the availability of chemicals, instruments, lab space, budget and other facilities, etc.

3. The department should complete a minimum of six practicals of each paper.
4. The workload of research project will be equivalent to the workload of 2 practical papers.
5. One theory paper will have 4 lectures each of 60 min. Duration per week and practical will have 6 hrs. duration.
6. There should be regular seminars and tutorials on immerging topics of subject concerned for students.
7. It is mandatory for students to have not less than 75% of attendance in each semester.
8. Department should organise lectures of subject experts and should also arrange study tours to industries and National research institutes.

**Dr. BABASAHEB AMBEDKAR  
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**REVISED SYLLABUS OF**

**M. SC. (MICROBIOLOGY)**

**SEMESTER - IV**



[Semester IV]

## **PAPER TH - XIII RECOMBINANT DNA TECHNOLOGY**

**Marks 50**

### **Unit – 1 Introduction, Core technique and Enzymes in gene manipulation**

Classical genetics to Modern Genetics, Approach of genetic engineering, advantages and limitations, Common steps in core technique. Enzymes in gene manipulations (DNA/RNA) : Classification, types, properties and mechanism of action of-Restriction endonuclease, ligase (T4 & E.coli ligase), Reverse transcriptase. Role of alkaline phosphatase, polynucleotide kinase ,Nucleotidyl transferase, Bal 31 and S1 nuclease, DNA polymerase, RNase , Ribozymes etc. in gene manipulation.

### **Unit-2 Tools and Techniques involved in genetic engineering**

Electrophoretic techniques in DNA analysis-Agarose gel electrophoresis, PAGE, Pulse field gel electrophoresis, DISC gel electrophoresis, electroelution, autoradiography, Restriction mapping, DNA sequencing-Maxam-Gilbert, Sanger's dideoxy and automated methods of DNA sequencing. Gene silencing, Principle, technique and applications of chromosome walking, chromosome jumping, RFLP, RAPD, AFLP, DNA fingerprinting  
Chromosome microdissection and microcloning, Microarray- principle, methodology, advantages and applications.

### **Unit-3 Vectors used in gene cloning**

Strategies of -Cloning vectors and expression vectors

Vectors of E.coli\_ : Plasmid vectors: Properties of plasmids, PBR 322-genetic evolution, map and function, pUC vectors

Phage vectors: Lambda phage vectors: gt phages , Charon vectors, EMBL vectors, M13 mp vectors

Higher capacity vectors: Cosmids, Phagmid bluescript vectors

High level expression/production vectors: PET vectors, PINPOINT vectors, BAC

Vectors for yeast : 2  $\mu$  plasmid vector, ARS vectors, mini chromosome vectors and YAC .

Shuttle vectors: SV 40 plasmid vectors, retrovirus vectors.

Vectors of plant: Ti plasmid vector

#### **Unit -4 Technique of gene cloning**

Isolation of gene of desired interest: Physical and Enzymatic using Restriction endonucleases, modification of cut ends, Chemical synthesis of genes and methods of joining the fragments into vectors, Ideal hosts in gene cloning, Different methods of transformation, Isolation of recombinant clones.

Construction of genomic and cDNA libraries: concept of library construction, differences and ideal examples of each library

Selection and Identification of clones containing recombinant vectors: Selectable and scorable markers, Insertional inactivation, colony hybridization, plaque lift assay, In Vitro translation:-Hybrid arrested translation, Hybrid release translation. Fluorescence activated cell sorter, southern hybridization, northern hybridization, Exon cloning, mini cells and maxi cells.

Screening for protein expression- Reporter gene expression, Phage display, south-western, Immunodiffusion, Radiolabelled antibody test, ELISA and western blotting

#### **Unit -5 Applications of genetic engineering and PCR**

Areas of applications of rDNA technology, Production of recombinant Insulin, Hepatitis B surface antigen, Production of monoclonal antibodies, rDNA in gene therapy (ADA Deficiency)

Construction of BT cotton plant and transgenic tomatos/potatos.

PCR alternative to gene cloning- advantages, principle and Procedure, optimization of PCR, Designing of primers, Identification of PCR products,

Variations in basic PCR- Inverse, asymmetrical , multiplex, Hot start, ligation mediated, RT , Real-time quantitative PCR, DD PCR and Immuno PCR.

Applications- DNA cloning for sequencing, DNA-based phylogeny, or functional analysis of genes; the diagnosis of hereditary diseases; the identification of genetic fingerprints (used in forensic sciences and paternity testing); the detection and diagnosis of infectious diseases. PCR based Site directed mutagenesis, Identification of pathogens.

**Paper - P-XIII**      **Practicals Based on**  
**RECOMBINANT DNA TECHNOLOGY**  
**Marks 25**

1. Isolation of Genomic DNA from *E. coli* & *Pseudomonas*.
2. Agarose Gel Electrophoresis.
3. Isolation of Plasmid DNA from *E. coli*.
4. DNA Denaturation and Determination of  $T_m$  and G + C content of Genomic DNA of *E. coli* & *Pseudomonas*.
5. Restriction Digestion of  $\lambda$  DNA.
6. Studies of Back Extraction of DNA by Electroelution.
7. Studies on Ligation Chain Reaction.
8. Gene Cloning: - Cloning of GFP Gene
9. Southern Hybridization.
10. Western Blotting.
11. RAPD – Rapid Amplification of Polymorphic DNA.
12. RFLP Analysis.

## References

1. Principles of Gene Manipulations 1994 by Old and Primrose Blackwell Scientific Publications.
2. DNA Cloning: A Practical Approach by D.M. Glover and B.D. Hames, IRL Press, Oxford. 1995.
3. Molecular Biotechnology 2nd Edition by S.B. Primrose. Blackwell Scientific Publishers, Oxford. 1994.
4. Genetic Engineering and Introduction to Gene Analysis and Exploitation in Eukaryotes by S.M. Kingsman and A.J. Kingsman, Blackwell Scientific Publications, Oxford 1998.
5. PCR Technology - Principles and Applications for DNA Amplification by Henry A. Erlich (Ed.) Stockton Press. 1989.
6. Biotechnology: A Guide to Genetic Engineering by Peters.
7. Weaver Molecular Biology.
8. Genetic Engineering – 2000 by Nicholl.
9. Recombinant DNA and Biotechnology: Guide for Teachers. 2nd Edition by Helen Kreuz. 2001 .ASM Publications.

10. Molecular Biotechnology: Principles and Applications of Recombinant DNA. 2 nd Edition. 1998 by Bernard R. Glick and Jack J. Pastemak, ASM Publications.
11. From genes to clones by Winnaker.
12. Manipulations and expression of recombinant DNA by Robertson.
13. Gene targeting – A practical approach by Joyner.

## **PAPER TH-XIV: FERMENTATION TECHNOLOGY**

Marks 50

### **Unit – 1 Microbial Fermentations**

Strain Improvement Programme, Media formulation, industrial production, Downstream Processing, Biosynthesis, Regulation and metabolic control of:

Organic acids -Citric acid, lactic acid

Enzymes - alpha-amylase, lipase, xylase, pectinases, proteases

Organic solvent - acetone- butanol and Vinegar fermentation.

Amino acids - lysine and glutamic acid.

### **Unit – 2 Microbial production of therapeutic compounds**

Strain Improvement Programme, Media formulation, industrial production, Downstream Processing, Biosynthesis, Regulation and metabolic control of: Penicillin, Streptomycin, Rifamycin and Tetracycline.  
Biotransformation of steroids, antibiotics..  
Vitamin B12 and riboflavin fermentation.

### **Unit – 3 Modern trends in microbial production**

Modern trends in microbial production of bioplastics (PHB, PHA), bioinsecticides (thuricide), biopolymer (dextran, alginate, xanthan, pullulan), Biofertilizers (nitrogen fixers and Phosphate solubilizers viz. Azotobacter, Rhizobium, Azolla, Water hyacinth; Field application of biofertilizer), Biosurfactants, Single Cell Protein and single cell oil.  
Bioterrorism (bacterial and viral weapons) – Historical events, types of biological agents, Modern bioterrorist incidents and limitations of bioterrorism.  
Mushroom cultivation.

### **Unit – 4 Biofuels and Plant Tissue Culture**

Useful features of bio-fuels. The substrate digester and the microorganisms in the process of biogas production (biomethanation). Production of bioethanol from sugar, molasses, starch and cellulosic materials. Microbial production of hydrogen gas, biodiesel from hydrocarbons.  
Introduction to cell and tissue culture, tissue culture media: composition and preparation, initiation and maintenance of callus and suspension culture, single cell clones, organogenesis: principle, concept and applications of somatic embryogenesis, embryo culture, anther, pollen and ovary culture for production of haploid plants and homozygous lines. Cryopreservation, slow growth and DNA banking for germplasm conservation.

## **Unit – 5 IPR and Patents**

Intellectual Property Rights (IPR), Patents - Patenting of biological materials, obligations with patent applications, implication of patenting, current issues, hybridoma technology etc., Trademarks, Copyrights, Secrets, Trademarks and geographical indications; IPR and plant genetic resources (PGRs) Patenting of higher plants and animals, transgenic organisms and isolated genes, patenting of genes and DNA sequences, plant breeders right and farmers rights.

### **PRACTICALS**

#### **PAPER P-XIV FERMENTATION TECHNOLOGY**

#### **Marks 25**

1. Citric acid fermentation by using *A. niger*,
  - a. Production and purification.
  - b. Qualitative detection by titratable acidity and paper chromatography.

- c. Quantitative estimation of citric acid by Pentabromoacetone method.
- d. Effect of different carbon, nitrogen sources and metal ions on citric acid production.
2. Microbial production of glutamic acid.
3. Production, purification and bioassay of Rifamycin/Streptomycin.
4. a. Production, distillation and estimation of ethanol using various Organic wastes /raw Material (e.g. agro wastes, different fruit juices, etc.) from free cells of yeast.  
b. Ethanol fermentation using immobilized yeast cells.
5. Production, extraction and bioassay of thuricide.
6. Laboratory scale production of biofertilizers [Nitrogen fixer/Phosphate Solubilizers].
7. Microbial production, purification, qualitative and quantitative estimation of polysaccharide from *Leuconostoc mesenteroides*/ *Pseudomonas*
8. Microbial production of single cell protein by algae/bacteria/yeast.
9. Bioassay of vitamin B12/B2.
10. Preparation of callus culture
11. Preparation of suspension culture

## **References: -**

1. Biotechnological Innovations in Chemical Synthesis. BIOTOL. Publishers / Butterworth - Heinemann.



2. Industrial Microbiology by G. Reed (Ed), CBS Publishers (AVI Publishing Co.)
3. Biology of Industrial Microorganisms by A.L. Demain.
4. Genetics and Biotechnology of Industrial Microorganisms by C.I. Hershey, S.W. Queener and Q. Hegeman. Publisher. ASM. Ewens ET. AL. 1998. Bioremediation Principles. Mac Graw Hill.
5. Annual Reports in Fermentation Processes by D. Pearlman, Academic Press.
6. Fundamentals of Biochemical Engineering by Bailey and Ollis.
7. Annual Review of Microbiology by Charles E. Clifton (Volumes)
8. Biotechnology, A textbook of industrial Microbiology by Creuger and Creuger, Sinauer associates.
9. Manual of industrial Microbiology and Biotechnology 2nd edition by Davis J.E. and Demain A.L. ASM publications.

## PAPER TH-XV

# **BIOINFORMATICS, MICROBIAL GENOMICS AND PROTEOMICS.**

## **UNIT- I BIOINFORMATICS AND ITS APPLICATIONS**

Introduction to Bioinformatics: Definition and History of Bioinformatics, Internet and Bioinformatics, relationship between molecular evolution and bioinformatics. Structure function relationship, Data Mining, Basic data structure, Databases: Types of Databases Nucleotide sequence databases; Primary nucleotide sequence databases- EMBL, GenBank, DDBJ. Secondary nucleotide sequence databases- UniGENE, SGD, EMI Genome, Genome Biology. Protein sequence database – SWISS PROT, TrEMBL, PIR, MIPS, NRL-3D Protein Family database – PFAM, PROSITE, PRINTS, BLOCKS, eMOTIF Protein Structure database – PDB, SCOP, CATH Composite database – NRDB, OWL, MIPS, SWISS-PROT + TrEMBL Bioinformatics Softwares: Clustal V, Clustal W 1.7, RasMol, Oligo, Molscript, Treeview, Alscript, Genetic Analysis Software, Phylip Search and retrieval of biological information and database sequence, Databank (PDB and GenBank) Accessing information (Network expasy, EMB Net, ICGEB Net) Protein domain and human genome analysis programme, Applications of Bioinformatics

## **UNIT – II WHOLE GENOME ANALYSIS**

Human genome project, uses and application, Genome information and special features, coding sequences, (CDS), Untranslated regions (UTR'S), cDNA library, Expressed sequence Tags (EST). Approach to gene identification, Preparation of ordered cosmid libraries, Bacterial Artificial Libraries, Shotgun Libraries and sequencing, Conventional sequencing (Sanger, Maxam and Gilbert method) Automated sequencing.

## **UNIT – III SEQUENCE ANALYSIS**

Algorithms; uses and applications, Local and Global sequence alignment.

Single Sequence Alignment; Pairwise alignment:

Scoring Matrix – PAM, BLOSUM, Gap penalty.

Dynamic programming – Needleman – Wunsch, Smith- waterman

Heuristic Methods- FASTA, BLAST for protein and nucleic acid.

Multiple Sequence Alignment;

ClustalW , PROFILE, PSI- BLAST, Hidden Markov Models (HMMs)

Annotation of Gene, Open reading frames (ORF), Conserved protein motifs related structure / function (PROSITE, PFAM, Profile Scan). protein motifs.

DNA analyses for repeats (Direct and inverted), palindromes, folding programmes. Use of Internet, public domain databases for nucleic acid and protein sequences (EMBL, GeneBank), database for protein structure (PDB).

#### **UNIT- IV DNA – MICROARRAY**

Concept of micro array, Spotted arrays, Oligonucleotide arrays, Designing the experiment, Two – colour micro array experiments, Computational analysis of microarray data.

Printing of oligonucleotide and PCR products on glass slides, nitrocellulose paper. Whole genome analysis for global patterns of gene expression using fluorescent labeled cDNA or end labeled RNA probes, analysis of SNP Using DNA chips.

Tools for microarray analysis:- Soft finder, xCluster, MADAM, SAGE. Advantage, disadvantage and application of DNA microarray. Introduction and tools to phylogenetic tree analysis.

## **UNIT- V PROTEOMICS**

Definition, Protein sequence information, composition and properties, physicochemical properties based on sequence, database, Two dimensional separation of total cellular protein, isolation and sequencing, Analysis individual protein spot by Mass spectroscopy

(MALDI- TOF), Electro Spray Ionization (ESI), Tandem mass spectroscopy (MS/MS) tryptic digestion and peptide Mass finger printing(PMF), 3D structure determination by X- ray and NMR. Protein identification programme – MASCOT, PeptIdent, Protein prospector, GFS. Advantage, disadvantage and application of protein microarray.

**PRACTICAL**  
**PAPER- P-XV: - BIOINFORMATICS, MICROBIAL GENOMICS**  
**AND PROTEOMICS.**

Use of Internet /software for sequence analysis of nucleotides and proteins.

1. Studies of public domain databases for nucleic acid and protein sequences.
2. Determination of protein structure (PDB) by using RASMOL, CN -3D software
3. Genome sequence analysis by using BLAST algorithm
4. Protein sequence analysis by using BLAST algorithm

## References

1. Bioinformatics. 1998 by Baxevanis
2. Bioinformatics 2000 by Higgins and Taylor OUP.
3. Nucleic acid Research 2001. Jan. Genome database issue.
4. The Internet and the new Biology: Tools for Genomics and Molecular Research by Peruski, Jr. and Peruske (ASM) 1997.
5. Functional Genomics. A Practical Approach Edited by Stephen P Hunt and Rick Liveey (OUP) 2000.
6. DNA microarrays: A practical approach edited by Mark Schena (OUP)
7. Bioinformatics - A Practical Guide to the Analysis of Genes and Proteins. 2nd Edition by Baxevanis.
8. Bioinformatics: Sequence, structure and Data Bank: A Practical Approach by Higgs.
9. Bioinformatics - from Genomes to drug. 2 volumes by Lenganer.
10. Bioinformatics Methods and Protocols - Misener.
11. Bioinformatics: Sequence and Genome analysis.
12. Introduction to Bioinformatics by Altwood.
13. Proteome Research: New Frontiers in Functional Genomics: Principles and Practices.
14. Genomics: The Science and Technology behind the human project.
15. Protein Biotechnology. Edited by Felix Franks. Humana Press, Totowa, New Jersey.
16. Protein Engineering: Principles and Practice by Cleland.
17. Computer analysis of sequence data by Colte.
18. Bioinformatics and molecular evolution – P.G. Higgs & T. K. Attwood, 2005 Blackwell Publishing
19. Bioinformatics by David Mount
20. Bioinformatics- Introduction to Bioinformatics by Pevzner
21. Microarray- Gene expression Data analysis by Causton, Brazma 2003 Blackwell Publishing
22. Essential Bioinformatics by JIN XIONG 2006 Cambridge University press.
23. Microarray Data Analysis Methods and Applications Edited by Michael J. Korenberg 2007 Humana Press Inc.

### **Web sites for Proteomics and Genomics**

1. [www.geneprot.com](http://www.geneprot.com).

2. [www.hybrigenis.com](http://www.hybrigenis.com)
3. [www.mdsproteomics.com](http://www.mdsproteomics.com)
4. [www.stromix.com](http://www.stromix.com)
5. [www.syrrix.com](http://www.syrrix.com)

**MARKS: - 50**

## **Paper XVI : Pharmaceutical Microbiology**

### **Unit I: Principles of Antimicrobial chemotherapy.**

Introduction and selection of antimicrobial agents

Concept of Bioassay, therapeutic index, MIC and LD<sub>50</sub>.

Penetrating defenses, as cellular permeability barriers, Cellular transport system and drug diffusion.

Definition and classification of antibiotics, with respect to their mechanism of action, Antibacterial spectrum, Structural activity and relationship (SAR), acquisition of drug resistance, pharmacokinetics and adverse drug effect  $\beta$ -Lactum (Penicillin, Amoxicillin, cefuroxime), aminoglycosides (Streptomycin, Gentamicin), Tetracyclines (Tetracyclin, doxycyclin), Macrolides (Erythromycin, Azethreomycin), Peptide antibiotics (Bacitracin, polymixin, ), Sulphonamides (sulfamethoxazole), co-trimoxazole and quinolones (ciprofloxacin) Chloramphenicol, trimethoprim.

### **Unit II: Molecular aspects of Antimicrobial Chemotherapy.**

Definition, classification, Mechanism of action and examples of chemical disinfectants, antiseptic and preservatives.

Definition, classification, Mechanism of action and examples of antiviral (Acyclovir, zidovudine), Antifungal (amphotericin B, Fluconazole) and Antitumor (Bleomycin, ductinomycin ) antibiotics.

Drug delivery system in gene therapy. Approaches and safety considerations associated with gene therapy. Immunological problems associated to gene therapy. Pre-requisites and candidate diseases for human gene therapy. Drug carrier, Macromolecular, cellular, and synthetic Viral and non viral mediated gene delivery.

Introduction, concept and types of drug targeting, cellular level events of drug targeting, targeting ligands, blood cell receptors for endogenous compounds/ ligands, carrier and vesicular system for targeting, specialized liposomes for cellular drug targeting.

### **Unit III: Microbial Production and spoilage of Pharmaceutical Products.**

Manufacturing procedure and in-process control of Pharmaceutical products: Bacterial and Viral vaccine, sterile injectables, Solid dosage forms, liquid orals and Ointments

New Vaccine production: DNA vaccines, synthetic, peptide vaccines, multivalent subunit vaccines, edible vaccines and their trials.

Microbial production and applications of therapeutic / diagnostic enzymes: Asparaginase, Streptokinase, beta lactamases

Microbial production contamination and spoilage of Pharmaceutical products (sterile injectables, ophthalmic preparations and implements) and their sterilization

Applications of Biosensors in pharmaceutical industries.

### **Unit IV: Regulatory Practices and Policies in Pharmaceutical Industries.**

FDA, Govt. regulatory practices and polices.

Concept of R & D and Financing R and D, Quality control and market planning.



Significance of IP, BP and USP.

Reimbursement of drugs, Biological and legislative aspects.

Rational drug design (Quantitative structure activity relation QSAR of drug) and computational aspect of drug design.

Screening and utilization of bioactive phytochemicals.

Patenting of drugs and Biological products

#### **Unit V: Quality Assurance and Validation.**

Regulatory aspects of QC, QA, and QM. GMP , GLP and CMP in Pharma Industry. ISO, WHO, USFDA certification. Microbial Limit test of Pharma products. Sterility testing , pyrogen testing and LAL test of Sterile Pharma products. Sterilization- heat, D- value, Z-value and survival curve, radioactive, gaseous and filtration. Chemical and biological indicators. Designing layout for microbiology laboratory.

Practicals based on

### **Paper XVI : Pharmaceutical Microbiology**

Marks: 25

1. Spectrophotometric/ Microbiological methods for the determination of Griseofulvin.
2. Microbial production and Bioassay of Penicillin.
3. Bioassay of Chloramphenicol/Streptomycin by plate assay method or turbidometric assay methods.
4. Screening, Production and assay of therapeutic enzymes: Glucose Oxidase/Asperginase/beta lactamase.
5. Treatment of bacterial cells with cetrimide, phenol, and detection of Leaky substances such as amino acids, nucleic acids as cytoplasmic membrane damaging substances.

6. Determination of MIC and LD50 of Ampicillin / Streptomycin.
7. Sterility testing by using *B. sterothermophilus*/ *B. subtilis*.
8. Testing for microbial contamination. Microbial loads from syrups, suspensions, creams, and other preparations, Determination of D-value and Z-value for heat sterilization in pharmaceuticals.
9. Determination of antimicrobial activity of chemical compounds (like phenol, resorcinol and formaldehydes) Comparison with standard products.

## **REFERENCES**

1. Pharmaceutical Microbiology- Edited by W. B. Hugo & A.R. Russel Sixth Edition. Blackwell Scientific Publications.
2. Lippincott's illustrative Reviews: Pharmacology Edition: 02 Maryjnycck by Lippincott's review Publisher Pheladelphia 1997.
3. Principles of medicinal chemistry Vol. 1 by Kadam S.S., Mahadik K.R., Bothra K.G. Edition: 18, Nirali Publication.
4. Pharmacognosy by Gokhle S.D., KoKate C.K.. Edition: 18, Nirali Publication.
5. Biotechnology – Expanding Horizon by B.D. Singh ., First Edition, Kalyani Publication, Delhi.

6. Analytical Microbiology- Edited by Fredrick Kavanagh volume I &II. Academic Press New York.
7. Pharmaceutical Biotechnology by S. P. Vyas & V.K. Dixit. CBS publishers & distributors, New Delhi.
8. Quinolone antimicrobial agents- Edited by David C. Hooper, John S. Wolfson. ASM Washington DC.
9. Quality control in the Pharmaceutical industry - Edited by Murray S. Cooper Vol. 2, Academic Press New York.
10. Biotechnology- Edited by H.J. Rhem & Reed, vol 4 VCH publications, Federal Republic of Germany.
11. Good manufacturing practices for Pharmaceuticals. By Sydney H. Willing, Murray M. Tuckerman, William S. Hitchings IV. Second edition MerceL Dekker NC New York.
12. Advances in Applied Biotechnology series Vol.10, Biopharmaceutical in transition., Industrial Biotechnology Association by Paine Webber,. Gulf Publishing Company Houston.
13. Drug carriers in biology & medicine Edited by Gregory Gregoriadis. Academic Press New York.
14. Quality Assurance in Microbiology by Rajesh Bhatia, Rattan Lal Ithpunjani. CBS publishers & distributors, New Delhi.