

DWARAKA DOSS GOVERDHAN DOSS VAISHNAV COLLEGE



DEPARTMENT OF MICROBIOLOGY

Choice Based credit system

ACADEMIC YEAR 2017 - 2018

Programme Name : M.Sc. Applied Microbiology

Programme Code : 26

Head

P.G. Research Department of Microbiology
Dwaraka Doss Goverdhan Doss
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Arumbakkam, Chennai-600 106.

PRINCIPAL

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Arumbakkam, Chennai - 600106.

I. FUNDAMENTALS OF MICROBIOLOGY AND MICROBIAL PHYSIOLOGY

Unit I: Taxonomy: Binomial nomenclature – Classification schemes- general characteristics used in classification, major approaches used in classification systems – classical, numerical, molecular approach and classification of bacteria - Bergey's manual of systematic bacteriology; classification of fungi – Alexopoulos; classification of algae – Fritch.

Unit II: Bacterial Anatomy and Growth: Bacterial anatomy, growth and nutritional requirements, growth media, staining methods – Gram, acid fast, metachromatic granules, nuclear staining, capsular; Pure culture techniques; Measurements of growth - growth curve, factors affecting growth.

Unit III: Sterilization and Disinfections: Principles of sterilization and disinfections; Physical agents: Dry heat, moist heat, radiation and filtration; Chemical agents: Gaseous, aldehydes phenol, alcohol and halogens; Selection and evaluation of disinfectants – Mechanism of disinfectants.

Unit IV: Energy and Metabolism: Concepts of energy – Thermodynamics - Entropy – Reversible chemical reaction – energy and oxidation – O/R potential – electron carriers – generation of energy – substrate level and oxidative phosphorylation – Electron transport chain. Concepts of metabolism: mechanism of ATP synthesis – pathways involved in substrate level phosphorylation – fermentation, respiration, EMP & other glycolytic pathways.

Unit V: Photosynthesis and Basic Instruments: Nature of photosynthesis – Photophosphorylation – photosystem of plants, algae, cyanobacteria; carbon dioxide fixation – ribulose diphosphate carboxylase; Instruments – Autoclave, laminar air flow, incubator, pH meter, colorimeter; Microscopy - Light, Dark field, Phase contrast, Fluorescent.

References:

1. Alexopoulos, C.J. and Mims, C.W. (1988). *Introductory Mycology*, 4th Edition. Wiley East Ltd: New Delhi.
2. Brock, T.D. and Madigan, M.T. (2014). *Biology of Microorganisms*, 14th Edition. Benjamin Cummings Publication Company: California.
3. Caldwell, D.R. (1995). *Microbial Physiology and metabolism*. Wm. C. Brown Publishers: USA.
4. Cappuccino, J.G. and Sharman, N. (2013). *Microbiology: A laboratory Manual*, 10th Edition. Benjamin Cummings Publication Company: California.
5. Holt, J.S., Kreig, N.R., Sneath, P.H.A and Williams, S.T. (2014). *Bergey's Manual of Determinative Bacteriology*, 9th Edition. Williams and Wilkins: Baltimore.
6. Joanne Willey and Linda Sherwood. (2014). *Prescott's Microbiology*, 7th Edition. McGraw Hill.Inc:US.
7. Moat A.G. and Foster, J.W. (2002). *Microbial Physiology*, 4th Edition. John Wiley & Sons: New York.
8. Nester, E.W., Roberts, C.V. and Nester, M.T. (1995). *Microbiology, A human perspective*. IWOA: U.S.A.
9. Pelczar, M.J., Chan, E.C.S. and Kreig, N.R. (2004). *Microbiology*, 5th Edition. Mc. Graw Hill. Inc: New York.
10. Rhodes, P.M.,Stanbury. (1997). *Applied Microbial Physiology*, 6th Edition. IRL Oxford University Press: Oxford.
11. Ronald M. Atlas. (1997). *Principles of Microbiology*, 2nd Edition. McGraw Hill.Inc: US.
12. White, D. (2000). *The physiology and biochemistry of Prokaryotes*, 2nd Edition. Oxford University Press, Oxford: NewYork.

Course Outcome

At the end of the course, the student will be able

- To emphasize the Classification Principles, and learn about the techniques to study the bacterial cell structure, nutritional requirements growth.
- Master in aseptic techniques and be able to safely and successfully perform routine culture handling duties.
- Understand how different types of microscopes work and how to use them for microbiological work.

II MEDICAL MICROBIOLOGY – I (Bacteriology and Mycology)

Unit I: Introduction to medical microbiology: Normal human micro flora – medically important microbes – infectious disease process – microbial virulence and virulence factors – laboratory diagnosis; process of sample collection, transport and examination of clinical specimens. Conventional and rapid methods for microbial diagnosis– antimicrobial susceptibility tests. Nosocomial infections and zoonotic infections.

Unit II: Bacteriology – Morphology, cultural characteristics, pathogenicity, lab diagnosis and treatment: *Staphylococcus aureus*, *Streptococcus pyogenes*, *Bacillus anthracis*, *Corynebacterium diphtheriae*, *Clostridium tetani*, *Clostridium botulinum*, *Mycobacterium tuberculosis*, *Mycobacterium leprae*, *Treponema pallidum*, *Leptospira*.

Unit III: Bacteriology - Morphology, cultural characteristics, pathogenicity, lab diagnosis and treatment: Enterobacter, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella typhi*, *Pseudomonas aeruginosa*, *Vibrio cholerae*, *Aeromonas hydrophilla*, *Bordetella pertusis*, *Yersinia pestis*, *Neisseria gonorrhoea*, Spirochetes, Rickettsiae, Chlamydiae and Bacterioids.

Unit IV: Mycology - Morphology and classification of medically important fungi – Isolation and identification of fungi from clinical specimens. Newer methods in diagnostic mycology. Antifungal drugs.

Unit V: Mycology - Superficial mycosis – tinea, piedra. Cutaneous mycosis – dermatophytoses. Subcutaneous mycosis – mycetoma, sporotrichosis. Systemic mycosis – aspergillosis, candidosis. Mycotoxins.

References:

1. Ananthanarayan. R. and Jayaram Paniker.C.K. (2005). *Text book of Microbiology*, 7th Edition. Orient longman: Chennai.
2. Collee, J.G., Duguid, J.P., Fraser, A.G. and Marimoin, B.P. (2011). *Mackie and Mc Cartney Practcial Medical Microbiology*, 13th Edition. Churchill Livingstone: London.
3. David Greenwood, Richard. C.D., Slack, John and Forrest Peutherer. (1992). *Medical Microbiology*. 16th Edition. ELBS with Churchill Livingstone: London.
4. Geo.F. Brooks., Karen. C. Carroll., Janet. S. Butel. and Stephen. A. Morse. (2007). *Jawetz, Melnick & Adelberg's Medical Microbiology*. C.A.Lange:Los Altos.
5. Jagadish Chander. (1996). *A text book of Medical Mycology*, Interprint: New Delhi.
6. Maloy, S.R., Cronan. Jr. J.E, Freifelder, D.(1998). *Microbial genetics*. Jones and Bartlett publishers: U K.
7. Tom Parker, M. and Leslie H. Collier. (1990). *Principles of Bacteriology, Virology and Immunity*. 8th Edition. Topley & Wilson's: USA.

Course Outcome

At the end of the course, the student will be able

- Assess the role of normal flora in the human body and gain knowledge of the human infections.
- Apply appropriate conventional and modern microbiological techniques, methodologies, instrumentation in accordance with diagnostic procedures.

III BASICS IN IMMUNOLOGY AND IMMUNOTECHNOLOGY

Unit I: Organs and Cells in Immune System and Immune Response: Primary lymphoid organs, secondary lymphoid organs and lymphoid tissues; T – cell and B –cell membrane bound receptors – apoptosis; T - cell processing, presentation and regulation; T –cell subpopulation, properties, functions and T – cell suppression; Physiology of immune response- innate, humoral and cell mediated immunity; Immunohaematology.

Unit II: Antigen and Antibody: Antigens - Properties of haptens, epitopes, adjuvants and cross reactivity; Antibodies- structure, properties, classes; **Antigen and Antibody Reactions: precipitation, agglutination, complement fixation, opsonisation, neutralization;** Vaccines – active and passive immunization; Classification of vaccines; Other approaches to new vaccines; Types of vaccine - antibacterial, antiviral; Vaccine schedule.

Unit III: Immunoassay and Immunotechniques: Preparation and standardization of bacterial antigens; Raising of monoclonal and polyclonal antibodies; Purification of antibodies. Immunotechniques: RIA, RAST, ELISA, Immuno fluorescence techniques and Flow cytometry.

Unit IV: Transplantation and Tumor immunology: MHC Antigens - structure and function; HLA system - Regulation and response to immune system; Transplantation immunology - tissue transplantation and grafting; Mechanism of graft acceptance and rejection; HLA typing; Tumor specific antigens; Immune response to tumors; Immune diagnosis; cancer immune therapy.

Unit V: Immunological disorders and diseases: Hyper sensitivity reactions (Type I, II, III and IV); Acquired Immunodeficiency syndrome; Auto immune disorders and diseases: organ specific and non organ specific.

References:

1. Chapel, H. and Halbey. (1986). *Essentials of Clinical Immunology*, ELBS: London.
2. Donald. M. Weir and John Steward. (1993). *Immunology*, 7th Edition. ELBS:London.
3. Hue Davis. (1997). *Introductory Immunology*, 1st Edition. Chapman & Hall Publisher: London.
4. Ivan.M. Roit. (1994). *Essential Immunology*. Blackwell Scientific Publications: Oxford.
5. Kuby. J. (1994). *Immunology*, 2nd Edition. W.H. Freeman and Co: New York.
6. Paul. (1998). *Fundamental Immunology*, 2nd Edition, Raver Press: New York.
7. Peter. J. Delves, and Ivan. M. Roit (eds). (1998). *Encyclopedia of Immunology*, 2nd Edition. Academic Press: San Diego.
8. Ridklad, M. Aydl. (1995). *Immunology*, 2nd Edition, NMS Publications: Baltimore, HongKong.
9. Riott. I .M. (1998). *Essentials of Immunology* .ELBS, Blackwell Scientific Publishers: London.
10. Roit, J.M.,Brostaff, J.J. and Male, D.K. (1996). *Immunology*, 4th Edition. C.V. Mosby Publisher: St. Loius.

Course Outcome

At the end of the course, the student will be able

- Investigate the immune system's various cells, as well as their responses to humoral and cell-mediated immunity and immunodeficiency diseases.
- To gain a better understanding on vaccine production and immunization schedule.
- Understand the various mechanisms involved in tissue and organ transplantation, immune response to tumor antigens and how immune responses have a role in hypersensitivity.

IV MOLECULAR BIOLOGY AND MICROBIAL GENETICS

Unit I: Chromosome organization in prokaryotes and eukaryotes: Nucleic Acids - structure of DNA and RNA; DNA as genetic material - forms of DNA; Replication, enzymes and proteins involved in DNA replication; Mutation, DNA damage and repair mechanism; Types of RNA.

UNIT II: Gene Transfer Mechanisms: Transformation, transduction, conjugation, recombination; Biology of Plasmids - Extra chromosomal heredity - biology of bacterial plasmids, structure of the plasmids, replication, control, partitioning, amplification, incompatibility and gene transfer; Transposons.

Unit III: Transcription: Basic features of genetic code, prokaryotic and eukaryotic ribosomes; General principles, basic apparatus, RNA polymerases, promoters, enhancers and other regulatory sequences; Mechanism of transcription and inhibitors of transcription; Post – transcriptional modifications.

Unit IV: Translation: Details of translation- initiation, elongation and termination, factors that control the above steps, inhibitors of protein synthesis; Post translational modifications: Protein folding, structural analysis, signal hypothesis protein targeting and secretion, *in vitro* transcription and translation systems.

Unit V: Regulation of gene expression in prokaryotes and Eukaryotes: Operon concept (*Lac* operon, *trp* operon, *ara* operon and *his* operon); Global regulatory responses: heat shock response, stringent response, SOS response and regulation; Eukaryotic translational control; translational control of gene expression; inhibitory RNA (RNAi); Hormone and environmental factors affecting gene expression.

References:

1. Bates, A.D, and Maxwell, A. (2006). *DNA Topology*, Indian Edition., Oxford University Press: New Delhi.

2. Brown, T.A.. (1995). *Essential Molecular Biology, Vol. I, A Practical Approach*, IRL Press, Oxford:UK.
3. Lewin, B. (2004). *Gene VIII*. Pearson Prentice Hall, Pearson Education, Inc.,NT: USA.
4. Maacinski, G.M. and Freifelder, D. (1998). *Essentials of Molecular Biology*, 3rd Edition, John and Bartlett Publishers: U S.
5. Malacinski, G.M. (2003). *Essentials of Molecular Biology*, 4th Edition, Jones & Batiett: London.
6. Maloy, S.R., Cronan, J.R. and Freifelder, D. (1994). *Microbial Genetics*. Jones and Bartlett Publishers: U S.
7. Nelson, D.L and Cox, M.M. (2005). *Lehninger's Principles of Biochemistry*, 4th Edition. McMillan Worth Publ. Inc: New York.
8. Oliver, R.P. and Schweizer, M. (1999). *Molecular Fungal Biology*. Cambridge University Press, Cambridge: UK.
9. Russell, P.J. (1998). *Genetics*, 5th Edition. Benjamin-Cummings Publ. Co. Inc: New York.
10. Turner, P.C., McLennan, A.G., Bates, A.D., and White, M.R.H. (2002). *Instant Notes: Molecular Biology*, 2nd Edition. Viva Books Pvt. Ltd: New Delhi.
11. Watson, J.D., Baker, J.A., Bell, S.P., Gann A, Lewin M. and Losick. R. (2004). *Molecular Biology of the Gene*. Benjamin Cummings- CSHL Press: USA.
12. Weaver, R.F.(1999). *Molecular Biology*. WCB McGraw-Hill Co. Inc: New York.
13. Wink, M. (2006). *An Introduction to Molecular Biotechnology*. Wiley-VCH Verlag Gmbh & Co: Germany.

Course Outcome

At the end of the course, the student will be able

- Understand the notion of molecular biology's basic dogma, have a conceptual understanding of DNA as a genetic material and can describe the structure and function of DNA and RNA in a cell.

- To explain the significance of gene transfer mechanism.
- Understand the molecular mechanisms involved in transcription and translation in prokaryotes and eukaryotes.

ELECTIVE I BIOINFORMATICS

Unit I: Introduction for information search and retrieval: Historical overview- applications of bioinformatics – major databases in bioinformatics – data management and analysis – tools for web search – data retrieval tools – data mining of biological databases.

Unit II: Sequence alignment: Methods (dot matrix, heuristics method); Scoring matrices (PAM – BLOSUM) sequence detection efficiency – methods of multiple alignment – evaluation and application - phylogenetic analysis (distance method – neighbourhood joining method – fitch maximum parsimony maximum likelihood) – tree evaluation – automated tools for of phylogenetic analysis.

Unit III: Tools for similarity search and Expression: **FASTA – BLAST;** Gene expression: DNA Microarray – clustering gene expression profiles – data sources and tools for microarray analysis –applications of microarray technology.

Unit IV: Genomics & Proteomics: SNPs, ESTs, GSS, Gene prediction tools - **Molecular Predictions with DNA sequence** - Human Genome Project; Proteomics: Protein classification approaches (SCOP – CATH) - Structure prediction - motifs, profiles, patterns and fingerprints search - Proteomics classification – tools and techniques in proteomics.

Unit V: Drug discovery and computer aided drug design: Introduction – SNPs – parameters in drug discovery - cell cycle target – identification and validation – drug discovery technology and strategies - identification of possible drug target molecules; GPCRs; **Drug design and approaches** – CAMD – DOCKING programmes – ADME property prediction.

References:

1. Arora, P.N and Malhon P.K. (1996). *Biostatistics*. Himalaya Publishing House: Mumbai.
2. Baxevanis, A.D. and Ouellette. B.F.F.(2001). *Bioinformatics: A practical guide to the analysis of genes and proteins*. Wiley Interscience : New York .
3. Cynthia Gibas and Per Jambeck. (2001). *Developing Bioinformatics Computer Skills*. Shroff Publishers & Distributors Pvt. Ltd: Mumbai.
4. Des Higgins and Willie Taylor. (2000). *Bioinformatics: Sequence, structure and databanks*. Oxford University Press: U K.
5. Felix Franks. (1993). *Protein Biotechnology*. Humana Press, Totowa: New Jersey.
6. Higgins and Taylor. (2000). *Bioinformatics*. Oxford University Press: U.K.
7. Mark Schena.(1999). *DNA microarrays: A practical approach*. Oxford University Press: U.K.
8. Nucleic acid Research. (2001). Genome database issue. Oxford University Press: U.K.
9. Peruski, Jr. and Peruske. (1997). *The Internet and the new Biology: Tools for Genomics and Molecular Research*. American Society of Microbiology: U.S.A.
10. Rashidi,.H.H. and Buehler, L.K.(2002). *Bioinformatics Basics: Applications in Biological Science and Medicine*. CRC Press: London.
11. Sokal and Rohif. (1973). *Introduction to Biostatistics*. Toppan Co: Japan.
12. Stanton, A .Glantz. (2011). *Primer of Biostatistics*, 7th Edition. The McGraw Hill Inc: New York.
13. Stephen, P. Hunt and Rick Liveey. (2000). *Functional Genomics. A Practical Approach*. Oxford University Press: U.K.

Course Outcome

At the end of the course, the student will be able

- Assess the computational methods, tools, and algorithms used in biological data interpretation, as well as phylogenetic analysis strategies and tools.
- To gain knowledge on existing software techniques to predict and understand the interaction between the genome's secondary protein structure,
- To assess various concepts, advanced technological docking tools, and QSAR research in computational drug development.

V FOOD, DAIRY AND INDUSTRIAL MICROBIOLOGY

Unit I: Preservation of food and Food Borne illnesses: Microbial contamination, preservation and spoilage of vegetables, fruits, poultry, fish, eggs, meat and meat products, canned foods; Food Preservation: Temperature (low and high), drying, radiation and chemicals; Food borne infections and intoxications: Intoxications - Staphylococcal and Clostridial; Infections: Bacterial - *Salmonella*, *Bacillus cereus*, *Vibrio parahaemolyticus*, *E.coli* 0157 and *Listeria* ; Non-bacterial- Mycotoxins, Viruses, Rickettsia.

Unit II: Industrial food fermentations: Bread, beer, wine and its type, sauerkraut, soysauce, Temph, Natto, Miso, Red rice and Idly.

Unit III: Dairy Microbiology: Contamination, preservation and spoilage of Milk and Milk Products – Yogurt, Cheese, Butter milk, Kefir, Komiss, Renin and Sweet Condensed Milk; Industrial production of Cheese and Yoghurt; Milk borne diseases.

Unit IV: Industrial Microbiology: Microbial production of organic acids: Citric acid, lactic acid and vinegar. Microbial Production of vitamins: B₁₂, B₂, C; Microbial production of amino acids: Glutamic acid and lysine.

Unit V: Quality assurance of Food: International Aspects of Quality and safety assessment of Foods; Microbiological Quality standards for Food; Government regulatory practices and policies: FDA, HACCP, BIS (IS), FSSAI-2014; Food adulteration and common food additives.

References:

1. Arora, D.K. (2004). *Handbook of Fungal Biotechnology*. 2nd Edition. Marcel Dekker Inc: USA.
2. Belits, H.D, and Grosch, W. (2009). *Food Chemistry*. 4th Edition. Springer Verlag: Germany.
3. Bielecki, S., Tramper, J. and Polak, J. (2000). *Food Biotechnology*. Elsevier: London.
4. Crueger, W. and Cruger, A. (2002). *Biotechnology: A Textbook of Industrial Microbiology*, 2nd Edition. Panima Publishing Corporation: New Delhi.
5. Demain, A.L. and Davies, J.E. (Editor in Chief). (1999). *Manual of Industrial Microbiology and Biotechnology*, 2nd Edition, ASM, Washington: USA.
6. Earrly, R. (1998). *The Technology of Dairy Products*. 2nd Edition. Blackie Academic & Professional.U.K.
7. Gupta, P.K. (2012). *Biotechnology and Genomics*, 1st Edition. Rastogi Publications: Meerut, India.
8. Jay, J.M and David A.Golden. (2006). *Modern Food Microbiology*, 7th Edition. Springer: U S.
9. Knorr, D. (1987). *Food Biotechnology*. Marcel Dekker, Inc: New York.
10. Marooka, Y. and Imanaka., T. (1994). *Recombinant Microbes for Industrial and Agricultural Applications*. Marcel Dekker, Inc: USA.
11. Satyanarayana, U. (2005) *.Biotechnology*. Uppala Author Publisher Interlinks: Vijaywada, India.
12. Singh, R. (2004). *Food Biotechnology*. Vol.1 & 2. Global Vision Publishing House: Delhi.

13. Spencer, J.F.T. and de, Spencer,A.L.R. (2001). *Food Microbiology Protocols*. Humana Press. NJ: USA.

14. Wood, R., Nilsson, A. and Wallin, H. (1998). *Quality in the Food Analysis Laboratory*. Royal Society of Chemistry: U K.

Course Outcome

At the end of the course, the student will be able

- Understand the mechanism of food deterioration and food preservation.
- Recognize the role of microorganisms in fermented foods and dairy products.
- Understand the relevance food safety regulations, regulatory bodies, and quality assurance programs such as FDA, HACCP, BIS, and FSSAI.

VI SOIL AND AGRICULTURAL MICROBIOLOGY

Unit I: Soil Microbiology: Soil structure – profile, texture; Formation– physical, chemical and biological; Types and classification; Importance of soil; Distribution of microbes in soil –bacteria, fungi, actinomycetes, protozoa and viruses; Methods to detect soil microbes.

Unit II: Nitrogen fixation: Biological nitrogen fixation – symbiotic, asymbiotic bacteria and blue green algae; Nitrogen fixation by nodulated plants other than legumes – NIF genes; Nitrification and denitrification processes; Soil amendments for higher fertility- denitrifiers and phosphate solubilizers; Soil enzymes.

Unit III: Abiotic and biotic interactions: Bio-geo chemical cycles – nitrogen, carbon, phosphorus, sulphur and iron cycle; Interaction among microbial populations - positive, negative interactions and interactions between diverse microbial populations; Microbial interactions with plants and animals- Mycorrhizae, Rhizosphere, Phyllosphere, Leaf nodulation, Stem nodulation and Rumen flora.

Unit IV: Plant diseases: Host parasitic relationship; Disease, causative agent, symptomology, **mode of action and preventive and control measures of bacterial** – Blight,

Smut, Rust; Fungal – Tikka, Leaf spots; **Viral** – Mosaic, Vein clearing, Leaf roll; Plant pathogens and their control.

Unit V: Microbial Remediation: Microbial biodegradation of agricultural products – starch, cellulose and hemi-cellulose; **Biodegradation of pesticides** – approaches to bioremediation – humic acid in soil mineralization; Organic matter decomposition; Composition of litter; Composting - Green manure and Farm yard manure.

References:

1. Allospe, D, and Scel, K.J. (1987). *Introduction to Biodeterioration*. ELBS: London.
2. Atlas Ronald, M., Bartha,R. and Richard. (1987). *Microbial Ecology*, 2nd Edition. Benjamin/Cummings Publishing Company: California.
3. Baker, K.H. and Herson, D.S. (1994). *Bioremediation*. MacGraw Hill Inc: NewYork.
4. Christon, J. Hursts, (Chief Editor). (2001). *A Manual of Environmental Microbiology*, 2nd Edition. ASM Publications: Pune.
5. Dirk, J., Eladas. V., Trevors, J.T and Wellington,E.M.H. (1997). *Modern Soil Microbiology*. Marcel Dekker INC: New York.
6. Eldowney, S., Hardman D.J., and Waite, S. (1993). *Pollution: Ecology and Biotreatment*. Longman Scientific Technical: London.
7. Eldowney, S., Hardman, D.J., Waite, D.J. and Waite, S. (1993). *Pollution: Ecology and Biotreatment*. Longman Scientific Technical: London.
8. Gabriel Bitton. (1994.) *Waste Water Microbiology* 2nd Edition.Wiley – Liss: New York.
9. Grant, W.D, and Long, P.L. (1981). *Environmental Microbiology*. Blackie Glasgow: London.
10. Lawrence, P., Wacekett, C. and Douglas Hershberger. (2000). *Biocatalysis and Biodegradation: Microbial transformation of organic compounds*. ASM Publications: Pune.
11. Metcalf and Eddy,Inc. (1995). *Waste Water Engineering - Treatment, Disposal and Re-use*. Tata MacGraw Hill: New Delhi.

12. Mitchel, R. (1992). *Environmental Microbiology*. Wiley – John Wiley and Sons. Inc. Publications: New York.
13. Trivedy.R.K. (1998). *Advances in Waste Water Treatment Technologies*. Volumes II and I. Global Science Publication: Rajkot.

Course Outcome

At the end of the course, the student will be able

- To gain knowledge on nitrogen fixers and phosphorus solubilizers in terms of soil fertility.
- To understand microbe-animal and plant interactions, positive and negative associations and biogeochemical cycles.
- To emphasize microbial biodegradation of organic and agricultural products.

VII MEDICAL MICROBIOLOGY –II (Parasitology and virology)

Unit I: Parasitology - Introduction and classification of parasites. Host parasite relationship. Laboratory techniques in parasitology. Lifecycle, pathogenicity lab diagnosis, treatment: *Entamoeba histolytica*, *Giardia*, *Trichomonas vaginalis*, *Trypanosoma*, *Lieshmania donovani*, *Plasmodium*.

Unit II: Parasitology - Lifecycle, pathogenicity, lab diagnosis, treatment: *Taenia solium*, *Taenia saginata*, *Fasciola hepatica*, *Fasciola buski*, *Schistosoma mansoni*, *Ascaris lumbricoids*, *Enterobious*, *Wucheraria bancrofti*. Drugs for parasitic infections.

Unit III: Virology – General properties and classification of viruses. Viral diagnosis and serology – methods used for viral quantification and enumeration. Antiviral drugs.

Unit IV: Virology - Epidemiology, life cycle pathogenicity, diagnosis and treatment of RNA Viruses: Picorna viruses, Rhabdo viruses, Retro viruses, Orthomyxo viruses, Paramyxo viruses, Morbilli viruses, Reo viruses.

Unit V: Virology - Epidemiology, life cycle, pathogenicity, **diagnosis** and treatment of DNA Viruses: Pox virus, Parvo virus, Hepatitis virus, Herpes virus, Epstein barr virus. Oncogenic viruses. Emerging viruses (Ebola, SARS, H1N1, Flavi virus).

References:

1. Ananthanarayan. R. and Jayaram Paniker.C.K. (2005). *Text book of Microbiology*, 7th Edition. Orient longman: Chennai.
2. Arora, D.R. and Aorora. B. (2002). *Medical Parasitology*, 1st Edition. CBS Publishers and Distributers, New Delhi.
3. Collee, J.G., Duguid, J.P., Fraser, A.G. and Marimoin, B.P. (2011). *Mackie and Mc Cartney Practcial Medical Microbiology*, 13th Edition. Churchill Livingstone: London.
4. Conrat, H.F., Kimball, P.C., and Levy, J.A. (1988). *Virology*.2nd Edition. Prentice Hall, Englewood Cliff: New Jersey.
5. David Greenwood, Richard. C.D., Slack, John and Forrest Peutherer. (1992). *Medical Microbiology*. 16th Edition. ELBS with Churchill Livingstone: London.
6. Dimmock, N.J. and Primrose, S.B. (1994). *Introduction to Modern Virology*, IVth Edition. Blackwell Scientific Publications: Oxford.
7. Flint, S.J., Enquist, L.W., Krung, R. Racaniello, V.R. and Skalka, A.M. (2000). *Principles of Virology, Molecular Biology, pathogenesis and control*, ASM Press: Washinton D.C.
8. Geo.F. Brooks., Karen. C. Carroll., Janet. S. Butel. and Stephen. A. Morse. (2007). *Jawetz, Melnick & Adelberg's Medical Microbiology*. C.A.Lange:Los Altos.
9. Maloy, S.R., Cronan. Jr. J.E, Freifelder, D.(1998). *Microbial genetics*. Jones and Bartlett publishers: U K.
10. Parija,S.C.(1996). *A Text Book of Medical Parasitology*, Orient Longman: Chennai.
11. Tom Parker, M. and Leslie H. Collier. (1990). *Principles of Bacteriology, Virology and Immunity*. 8th Edition. Topley & Wilson's: USA.

Course Outcome

At the end of the course, the student will be able

- Learn about the parasitic infections in terms of identification, pathogenicity and diagnosis and treatment.
- To inculcate knowledge on various viral diseases and diagnostic procedures.

VIII PHARMACEUTICAL MICROBIOLOGY

Unit I: Introduction to Pharmaceutical microbiology: Ecology of microorganisms in pharmaceutical industry: Atmosphere, water, skin, respiratory flora of workers, raw materials, packaging, building and equipments and their control measures; Design and layout of sterile manufacturing unit.

Unit II: Microbial contamination and spoilage of pharmaceutical products: Microbial aspects of pharmaceutical products; Sterilization of pharmaceutical products: Heat, gaseous, radiation and filtration; Contamination and Spoilage of Pharmaceutical products: sterile injectable and non-injectable, ophthalmologic preparation, implants.

Unit III: Production of antibiotics: Production of antibacterial – Penicillin, Tetracycline; antifungal – Griseofulvin, Amphotericin; antiparasitic agents – Artemesin, Metronidazole; Semi-synthetic antibiotics and anticancerous agents; Additional application of microorganisms in pharmaceutical sciences: Enzymes- Streptokinase, Streptodornase, L-asperginase and clinical dextrin; Immobilization procedures for pharmaceutical applications (liposomes); Biosensors in pharmaceuticals.

Unit IV: Production of immunological products and their quality control: Vaccines - DNA vaccines, synthetic peptide vaccines, multivalent subunit vaccines; Vaccine clinical trials; Immunodiagnostic - immuno sera and immunoglobulin; Quality control in Pharmaceutical: In – Process and Final Product Control; Sterility tests.

Unit V: Quality Assurance and Validation: Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) in pharmaceutical industry; Regulatory aspects of quality control; **Quality assurance and quality management in pharmaceuticals** – BIS (IS), ISI, ISO, WHO and US certification.

References:

1. David, C. Hooper, and John.S.Wolfson. (2005). *Quinolone antimicrobial agents*. ASM: Washington.
2. Frederick Kavanagh.(2014). *Analytical Microbiology*, Volume I & II. Academic Press: New York.
3. Gregory Gregoriadis.(2011). *Drug Carriers in biology & Medicine*. Academic Press: New York.
4. Hugo,W.B, and Russel.A.D. (2003). *Pharmaceutical Microbiology*, 6th Edition. Blackwell Scientific Publications: U K.
5. Murray, S.Cooper. (1991). *Quality control in the Pharmaceutical Industry*, Vol.2. Academic Press: New York.
6. Rajesh Bhatia and Rattan Lal. (2000). *Quality Assurance in Microbiology*. CBS Publishers: New Delhi.
7. Rehm,H.J. and Reed.G. (2010). *Biotechnology*, Volume 4.VCH Publications: Federal Republic of Germany.
8. Sambamurthy,K.(2006). *Pharmaceutical Biotechnology*. New Age International: New Delhi.
9. Vyas,S.P. and Dixit.V.K. (2011). *Pharmaceutical Biotechnology*.CBS Publishers: New Delhi.

Course Outcome

At the end of the course, the student will be able

- Acquire indepth knowledge in spoilage and contamination of pharmaceutical products.
- To gain knowledge on production of antibiotics, therapeutic enzymes and other pharmaceutical formulations.

- To emphasize quality assurance and quality management in pharmaceuticals according to various national and international standards.

ELECTIVE II TISSUE BIOTECHNOLOGY

Unit I: Introduction to tissue culturing: Basic concepts in cell culture; *In-vitro* culture: Approaches & methodologies - preparatory steps for tissue culture - surface sterilization of plant tissue material - basic procedure for aseptic tissue transfer - incubation of culture.

Unit II: Tissue nutrition: Growth Hormones - Plant cells (Composition of culture media, Growth Hormones, Vitamins, Unidentified supplements, selection of media); Animal cells (substrate on which cells grow, Feeder layer on substrate, gas phase for tissue culture, media and supplements).

Unit III: Tissue culture methodologies: Plant cells (Callus Culture, Cell Suspension Culture, and Organ Micro-Culture, Plant micro-propagation, Somatic Embryogenesis); Applications of plant tissue and cell culture; Animal cells (Source of tissue, Primary culture, and differentiation of cells - growth kinetics - animal cell lines) and their origin and Characterization applications of animal tissue culture.

Unit IV: Cloning & Selection: Cloning and selection of specific cell types – cloning, somatic cell fusion and HAT selection - Medium suspension fusion - selection of Hybrid clone - production of monoclonal antibodies.

Unit V: Cell Culture: Primary cultures and cell lines with examples - Stem cell cultures - Therapeutic cloning - Carcinoma stem cells - Germ cell culture – Uses; Organ culture - Culture of embryonic organs - whole embryo culture - culture of adult organs; Application of Tissue Biotechnology in animals, plants – medicines.

References:

1. Colin Ratledge and Bjorn Kristiansen. (2001). *Basic Biotechnology*. Cambridge University Press: U K.

2. Das, H.K. (2007). *Text book of Biotechnology*, 3rd Edition. Wiley India Pvt Ltd: New Delhi.
3. Gangal and Sudhda.(2010). *Principles and practice of animal tissue culture*, 2nd Edition. Universities Press Pvt,Ltd: India.
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5. Paul, F., Jr. Kruse, and Paterson, M..K. (2012). *Tissue Culture: Methods and Applications*. Academic Press: U.S.
6. Primrose, S.B. (2001). *Molecular Biotechnology*, 2nd Edition. Panima Publishing Corporation: India.
7. Razdan, M..K. (2003). *Introduction to Plant tissue culture*, 2nd Edition. Science publishers: USA.
8. Tomes, D.T. (1982). *Application of plant cell and tissue culture to agriculture and industry*. University of Guelph: Canada.
9. Yadav, P.R and Rajiv Tyagi.(2006). *Biotechnology of Animal Tissues*. Discovery Publishing company: New Delhi.
10. Yadav, P.R and Rajiv Tyagi.(2006). *Biotechnology of Plant Tissues*. Discovery Publishing company: New Delhi.

Course Outcome

At the end of the course, the student will be able

- Discover the techniques and aseptic procedures involved in tissue culture.
- To gain knowledge on plant and animal cell culture.
- Understand the advantages of cloning and hybridoma technologies, Stem cell cultures and Therapeutic cloning.

IX BIOINSTRUMENTATION

Unit I: Centrifugation techniques: Basic principles of centrifugation - standard sedimentation coefficient - measurement of sedimentation co-efficient;, Principles, methodology and application of differential, rate zonal and density gradient centrifugation - Applications in determination of molecular weight.

UNIT II: Chromatography: General principles of chromatography - Chromatographic Performance parameters; Types- Thin layer chromatography, Paper Chromatography, Liquid chromatography (LPLC & HPLC), Adsorption, ion exchange, Gel filtration, affinity, Gas liquid (GLC).

UNIT III: Electrophoresis: General principles - moving boundary electrophoresis - electrophoretic mobility – supportive materials – electro endosmosis – types (horizontal, vertical and two dimensional electrophoresis) - Principle and application paper electrophoresis, Serum electrophoresis, starch gel electrophoresis, Disc gel, Agarose gel, PAGE, SDS – PAGE, Immuno electrophoresis; Blotting techniques -Southern, northern and western blotting.

UNIT IV Spectroscopic techniques: Principle, simple theory of absorption of light by molecules, electromagnetic spectrum, instrumentation and application of UV- visible, Raman, FTIR spectrophotometer, spectrofluorimetry, Atomic Absorption Spectrophotometer, Flame spectrophotometer, NMR, ESR, Emission Flame Photometry and GC-MS.

UNIT V: Radioisotopic techniques: Principle and applications of tracer techniques in biology. Radioactive isotopes - radioactive decay; Detection and measurement of radioactivity using ionization chamber, proportional chamber, Geiger- Muller and Scintillation counters, auto radiography and its applications. Commonly used isotopes in biology, labeling procedures and safety aspects.

References:

1. Chapma, J.M and Ayrey, G. (1981). *The use of radioactive isotopes in the life sciences*. HarperCollins Publishers Ltd: London.
2. Chatwal, G. and Anan, (1989). *Instrumental Methods of Chemical Analysis*. Himalaya Publishing House: Mumbai.

3. Gordon, M. Message.(1984). *Practical aspects of Gas Chromatography and Mass Spectrometry*. John Wiley and Sons: New York.
4. Hames,.B.D. (1998). *Gel Electrophoresis of Proteins- A Practical Approach*, 3rd Edition. OUP: Oxford.
5. Hamilton, R.J and Sewell,.P.A.(1982). *Introduction to High Performance Liquid Chromatography*. Chapman and Hall: London.
6. James Miller. (1988).*Chromatography: Concepts and Contrasts*. John Wiley and Sons. Inc: New York.
7. Jeffery, G.H., Bassett. J., Mendham.J, and Denney, R.C. (1989). *Vogel's Text book of quantitative inorganic analysis*, 5th Edition. Longman Scientific & Technical: U K.
8. Straughan,B.B and Walker.S. (1976). *Spectroscopy*, Volume 1. Chapman and Hall Ltd: London.
9. Thornburn,C.C. (2010). *Isotopes and radiations in Biology*. Butterworth and Co. Ltd: London.
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11. Willard, H.H. (1988).*Instrumental Methods of Analysis*, 7th Edition. Wadsworth Publishing Company: California.
12. Williams, B.L. and Wilson, K.(1995).*A Biologists Guide to Principles and Techniques of Practical Biochemistry*. John Chanda: Zambia.
13. Wilson, K and Walker J. (2006). *Principles and Techniques of Biochemistry and Molecular Biology*, 6th Edition. Cambridge University Press: U K.

Course Outcome

At the end of the course, the student will be able examine the significance of advanced biochemical instrumentation techniques in modern research and their applications by learning about the concepts, applications, benefits, and limitations of typical biological lab tools. Understand various molecular spectroscopy's concepts, principles, instruments, operations, and applications in biomedical sciences. Improve the ability to carry out

research activities by learning basic and advanced chromatographic purification processes, gel electrophoresis.

X RECOMBINANT DNA TECHNOLOGY

Unit I: Introduction to Recombinant DNA technology: Basic techniques - Enzymes used in rDNA technology; Cloning vectors: plasmid (pUC19, pBR 322 and their derivatives), phage, cosmid, Phasmid (Lambda Zap); Shuttle /transfer vectors; High capacity Cloning vectors: BAC and YACs; Expression vectors: Prokaryotic - pET, pGEX-2T and others); Marker genes: Selectable markers and Screenable markers, nonantibiotic markers.

Unit II: Gene cloning strategies: Cohesive end cloning & blunt end cloning - Shot gun cloning and directed cloning - genomic DNA cloning library and cDNA cloning library; Preparation of rDNA molecule and its transfer to appropriate host (bacteria/yeast/plant cell/animal cell) using a suitable technique: transformation, electroporation, transfection, gene gun, Particle bombardment etc. Screening of Gene libraries for recombinant clones.

Unit III: Other rDNA techniques: Use of radioactive and non - radioactive nucleotides for DNA probe preparation and detection of hybrids; Restriction mapping; RFLP, PCR, RT-PCR, Real time PCR and its applications, DNA micro arrays and their use in Genomics; DNA sequencing: Maxam Gillbert, Sanger's method and automated sequencer; Chromosomal walking; Hybrid release and hybrid arrest translation to screen the clones - site directed mutagenesis.

Unit IV: Gene cloning systems/Hosts: Gene cloning in *E. coli* and other organisms such as *Bacillus subtilis*, *Saccharomyces cerevisiae* and other microbial eukaryotes. Gene manipulation in animals - transgenic mice and plants.

Unit V: Application of Genetic Engineering: Screening of Genetic diseases using DNA probes; Gene therapy; Molecular basis of genetic diseases, genetic counseling; DNA

typing and finger printing; Production of recombinant proteins and drugs - insulin, tissue plasminogen activator, erythropoietin, human growth hormones, vaccines, interferons; DNA vaccines and Edible vaccines.

References:

1. Balasubramanian, D., Bryce, C., Dharmalingam, K., Green, J. and Jayaraman, K. (1996). *Concepts in Biotechnology*. University Press: India.
2. Brown, T.A. (2001). *Gene Cloning*. 4th Edition. Chapman and Hall Publications: USA.
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11. Walsh, G. and Headon, D. (1994). *Protein Biotechnology*. John Wiley and Sons: New York.
12. Winnaker, E.L. (1987). *From genes to Clones: Introduction to Gene technology*. 3rd Edition. VCH Publications: Federal Republic of Germany.

Course Outcome

At the end of the course, the student will be able to validate knowledge of genetic engineering tools and techniques, as well as the usage of various cloning vectors and understand the fundamentals and concepts of rDNA cloning techniques. Learn about the many ways of gene transfer. Educate advanced molecular techniques like DNA finger printing, RFLP and their biological applications to meet international standards.

XI MICROBIAL PRODUCTS

Unit I: Production of microbial metabolites: Metabolic pathways and control mechanisms of primary and secondary metabolites; Commercially important metabolites: Primary – ethanol, citric acid; Secondary – antibiotics, β exotoxin; Probiotics and prebiotics; Bio preservatives of microbial origin; Plant growth hormones: Auxine, IAA, gibberlic acid.

Unit II: Single Cell Protein and Biofertilizers: Algae (*Spirullina maxima*, *Chlorella pyrenoidosa*), Bacteria (*Achromobacter delvacvate*, *Cellulomonas*), Fungi (*Trichoderma viride*, *Paecilomyces varioti*), Yeast (*Candida tropicalis*) as SCP, Mushroom Cultivation. Biofertilizers - Mass Production of *Rhizobium*, *Azetobacter*, *Azospirillum*, *Phosphobacterium*, BGA (*Anabena*, *Nostoc*); Packing, Quality assurance, Field Application and Crop Response.

Unit III: Bioinsecticide: Mass Production, field Application, and Crop Response of Bacteria (*Bacillus thuringiensis*, *Bacillus papillae*, *Pseudomonas fluorescens*), Fungi (*Verticillium lecanii*, *Coelomyces*) and Viruses (*Bacuulo viruses*, *NPV*, *Granulosis virus*), Entamopathogenic Fungi, Microbial Herbicides (*Alternaria cucutacidae*; *Puccinia chondrillina*)

Unit IV: Commercial Products: Production and Application of TPA, HGH, Cytokines and Monoclonal Antibodies; Production of enzymes – Cellulase, Protease, Amylase and lipase; Antimicrobial products from herbs: Neem, Thulasi, Turmeric, Aloe vera

Unit V: Biofuels, Bioplastics and Biopigments: Biochemistry, Industrial Production and Application of biogas, bio-diesel, hydrogen fuel, gasoline; **Bioplastics - PHB, PHA; Biopigments – Lycopene, Betacarotene,** Astaxanthin, Monascorubramin, Rubrolone, Phycocyanin and its applications.

References:

1. Ahmad, W.A., Wan Ahamad. W.Y., Zakaria,Z.A. and Yusof, N.Z. (2011) . *Microbial Pigments Application of Bacterial Pigments as colorants– Malaysian Perseptive*. Springer Science and Business Media: New York.
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12. Subash Chand, and Jain,S.C. (1998). *Fermentation Biotechnology: Industrial Perspectives*. All India Biotech Association: New Delhi.

Course Outcome

At the end of the course, the student will be able to boost entrepreneurial skills in developing various economically important products from microorganisms. To gain an understanding in various quality assurance concepts.

XII BIOPROCESS TECHNOLOGY

Unit I: Introduction to Bioprocesses: Historical development of bioprocess technology -traditional and modern applications of fermentation technology - range of fermentation processes - primary and secondary metabolites - components of fermentation process; Approaches to metabolic engineering.

Unit II: Industrially important microbes: Screening methods for industrial microbes – strain selection and improvement- GRAS - Mutation and recombinant DNA techniques for strain development and preservation; Media requirements - Carbon, nitrogen, minerals, vitamins and other complex nutrients, oxygen requirements; Medium formulation - commercial media for industrial fermentations; Cell and enzyme immobilization; Sterilization of media.

Unit III: Bioreactor design and operation: Classification of reactors; Ideal mixed v/s plug flow reactor; Designing parameters for reactors (stirred tank reactor, airlift reactor, plug flow reactor); Rheology of fermentation broth, gas-liquid mass transfer, heat transfer; analysis of dimension less parameters and their application (aeration number, power number and Reynold's number); Parameters used in scale-up and problems associated with scale-up.

Unit IV: Types of fermentations and their control: Batch, continuous, fed-batch, solid state, sub-merged; Aerobic, anaerobic, dual and multiple fermentations - advantages and disadvantages; Fermentation monitor and control: On-line and off-line analysis, digital controllers, control algorithm, flow charting, incubation control, advanced fermentation control and computer - based automation of process.

Unit V: Downstream processing: Biomass separation - centrifugation, filtration, flocculation and other recent developments. Cell disintegration: Physical, chemical and enzymatic methods. Extraction: Solvent, two phase, liquid extraction, whole broth, aqueous multiphase extraction; Purification by different methods - concentration by precipitation, ultra-filtration, reverse osmosis; Drying and crystallization.

References:

1. Alexander, N. Glazer and Hiroshi Nikaido. (2007). *Microbial Biotechnology: Fundamentals of Applied Microbiology*, 2nd Edition. W.N. Freeman and Co: London.
2. Ali Cinar., Satish J. Parulekar., Cenk Undey, and Birol Gulnur. (2003). *Batch Fermentation: Modeling, Monitoring, and Control*. Marcel Dekker Inc: New York.
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14. Stanbury, P.F., Whitaker, .A. and Hal,S.J. (1995). *Principle of Fermentation Technology*, 2nd Edition. Butter worth and Heinemann: Oxford.

Course Outcome

At the end of the course, the student will be able to develop skills on various upstream and downstream processes. To understand the implementation of various techniques in bioprocess industries.

ELECTIVE III NANOBIO TECHNOLOGY

UNIT I: Introduction and history of Nanotechnology: Nanomaterials: History - Properties - optical, electronic, magnetic properties; Surface plasmon resonance, Change of band gap; Types - nanowires, nanoclusters, Carbon nanostructures: DLCs, Fullerenes, C60, C80 SWNT and MWNT - thin films and multilayers. nanocomposites, nanofillers.

UNIT II: Chemical and Physical Synthesis: Chemical precipitation; Sol-gel synthesis; Micro emulsions or reverse micelles; Solvothermal synthesis; Physical methods: Inert gas condensation, Ion sputtering, pyrolysis.

UNIT III: Biological methods: Use of bacteria, fungi, actinomycetes and plants for nanoparticle synthesis; Magnetotactic bacteria for natural synthesis of magnetic nanoparticles; Mechanism of formation; Viruses as components for the formation of nanostructured materials; **Synthesis process and application.**

UNIT IV: Protein and Peptide based Nanostructures: DNA based nanostructures: DNA-protein nanostructure; Functionalization of nanoparticles for biological applications;

Characterization of nanomaterials: UV - VIS – FTIR – RAMAN spectroscopy; X-ray diffraction, HR- SEM, HR -TEM and EDAX analysis.

UNIT V: Challenges to nanotechnology: Applications of nanobiotechnology in medicine, agriculture and environment; Public and private investment in R&D, Materials risks (carbon fullerene and CNT waste); Methods of environmental monitoring and pollution control using nanotechnology.

References:

1. Chad, A. Mirkin and Christof, M. Niemeyer.(2007). *Nanobiotechnology II: More Concepts and Applications*. John Wiley and Sons: New York.
2. Christof, M. Niemeyer and Chad, A. Mirkin. (2004). *Nanobiotechnology: Concepts, Applications and Perspective*. Wiley Publications: New York.
3. Elisabeth, S. Pappazoglou and Aravind Parthasarathy. (2007). *Bio Nanotechnology*. Morgan and Claypool Publishers: California.
4. Goonsalves, E., Craig. R. Halberstadt., Cate. T. Laurecin, and Lakshmi, S.Nair. (2007). *Biomedical Nanostructures*.Wiley: New Jersey.
5. Martin and Donald. (2007). *Nanobiotechnology of biomimetic membranes*,1st Edition. Springer Verlag Publishers:U S.
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8. Ratner and Ratner.(2002). *Nanotechnology - A Gentle Introduction to the Next Big Idea*,1st Edition. Prentice Hall PTR: New Jersey.

Course Outcome

At the end of the course, the student will be able to understand the interactions between biomolecules and nanoparticle surfaces, as well as their applications, by learning about the many methods of nanoparticle creation, including physical, chemical, and biological

processes. Gain a solid understanding of the principles of a variety of physical and chemical characterization techniques.

ELECTIVE IV BIOSAFTEY AND CLINICAL RESEARCH

UNIT I: Bioassay: Biological standardization - general principles - Scope and limitation of bio-assay; Biological evaluation of drugs- development of models for diseases: *In vivo* models / *In vitro* models / cell line study; Microbiological quality and regulatory requirements for natural Biotherapeutics, nutraceutical products, vaccines, antibiotics; Pyrogen tests.

UNIT II: Biosafety: Safe laboratory practices -handling & storage of chemicals, reagents, microbial specimens and its preservation - risk assessment and risk management – risk groups – biosafety guidelines and regulations (National and International) – types of biosafety containments (level I, II, III) – segregation and disposal of noninfectious and infectious wastes, safety of personnel, protective equipment, emergency response; Biological hazards - types of contamination and control.

UNIT III: Clinical Research: Clinical evaluation of new drugs - Phases of clinical trial - Clinical Research - objectives and Protocols; US- FDA & ICH guideline for Clinical trials for drugs & dosage forms - Reviews & approval of clinical study - Good clinical practices.

UNIT IV: Introduction to ethics and bioethics: Personal ethics - Profession and professionalism – Moral Reasoning – Ethical theories – person as an experimenter - Moral leadership (integrity and ingenuity) - Framework for ethical decision making - Ethics in human research.

UNIT V: Intellectual property rights: Introduction - Types of intellectual property rights (patents, copy rights, trade mark, geographical indications, industrial designs and trade secret); Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005;

US and European Patent System - importance of IPR – patentable and non-patentable – legal protection of biotechnological inventions – world intellectual property rights organization (WIPO).

References:

1. Anna. S. Iltis and Sandra. H. Johnson. (2007). *Legal Perspectives in Bioetics*. Routledge Publications: New Delhi.
2. David Machin, Simon Day and Sylvan green. (2004). *Textbook of clinical trials*, 2nd Edition. Wiley Publications: New York.
3. Deepa Goel and Shomini Parashar. (2013). *IPR, Biosaftey and Bioethics*.1st Edition. Pearson education: Chennai.
4. Giovanna di ignazio., Di Giovanna and Haynes.(2001). *Principles of clinical research*, 1st Edition. Routledge Publications: New Delhi.
5. Hugo.W.B. and Russel. A.D. (1992). *Pharmaceutical Microbiology*, 5 th Edition . Blackwell Scientific Publications: London.
6. John, I. Gallin, Frederick P. Ognibene. (2012). *Principles and Practise of Clinical Rearch*. 3rd Edition. Academic press: U S.
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8. Richard. Ed.Prince. (2008). *Microbiology in Pharmaceutical Manufacturing*, Volume 1.Davis Harwood International Publishing: U K.
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12. Vijay Malik. (2014). *Drugs and Cosmetics act*, 24th Edition. Eastern Book Company publications: New Delhi.

Course Outcome

At the end of the course, the student will be able to develop knowledge on laboratory risks and implementation of biosafety procedures. To independently execute bioassay techniques for biotherapeutics, nutraceutical products, vaccines and antibiotics.