Rayat Shikshan Sanstha's

YASHAVANTRAO CHAVAN INSTITUTE OF SCIENCE, SATARA

(An Autonomous College)

Reaccredited by NAAC with 'A+' Grade

New Syllabus For

Master of Science

Part - II

APPLIED MICROBIOLOGY

Syllabus

To be Implemented from June, 2022 onward

M.Sc. Part II Semester III

Nature of the Course	Course code	Name of the Course
Theory	MAMiT 301	MICROBIAL ECOLOGY AND EXTREMOPHILES
	MAMiT 302	ESSENTIALS OF IMMUNOLOGY
	MAMiT 303	PHARMACEUTICAL MICROBIOLOGY
	MAMiT 304	FOOD AND DAIRY TECHNOLOGY
Practical	MAMiP 305	PRACTICAL COURSE III: LAB V
	MAMiP 306	PRACTICAL COURSE III: LAB VI

Semester IV

Nature of theCourse	Course code	Name of the Course
Theory	MAMiT 401	INDUSTRIAL MICROBIOLOGY
	MAMiT 402	MICROBIOLOGICAL QUALITY CONTROL AND ASSURANCE.
	MAMiT 403	GENE TECHNOLOGY AND GENOMICS
	MAMiT 404	ADVANCED BIOINFORMATICS
Practical	MAMiP 405	PRACTICAL COURSE IV: LAB VII
	MAMiP 406	PRACTICAL COURSE IV: LAB VIII

SEMESTER III
MAMiT 301: MICROBIAL ECOLOGY AND EXTREMOPHILES

Course Objectives: Student will able to :-

1. Understand the significance of microbial ecology.
2. Study ecology as a tool for global sustainability.
3. Understand the applications of extremophiles.
4. Study the human microflora and its effects on health.

Credits=4	**SEMESTER-III** **MAMiT 301: MICROBIAL ECOLOGY and EXTREMOPHILES**	**No. of hours per unit/ credits**
Credit –I **UNIT I**	**Basic Concepts of Microbial Ecology**	**(15)**
	A) **Microbial Ecology** – Definition, Concepts, **Community**- Definition, types, **Concepts-** structural and functional, **Ecological succession**- theories, types, significance, **Definitions:** niche, habitat, ecosystem. Interactions between microorganisms. B) Quantitative ecology i) Sample collection- soil, water, air, sediment, biological samples ii) Sample processing iii) Determination of microbial number a) Direct count b) Viable count procedure-Plate count and MPN	
Credit –1 **UNIT II**	**Recent Concepts in Microbial Ecology**	**(15)**
	A) Microbial biofilm – i) Physiology, morphology, biochemistry of microbial biofilm formed in natural environment. ii) Mechanism of microbial adherence. iii) Laboratory methods used to obtain biofilm (with respect to physiology, growth, special arrangement, depth, surface physio-chemistry) B) Beneficial and harmful role of biofilms.	

	C) Biomimicry – Concept and Applications. D) Bioremediation and Biodegradation - i) Engineering and bioremediation process its needs and limitations. Molecular technique in Bioremediation. ii) Degradation of aromatic and alicyclic compounds- important organisms, use of mixed cultures in common pathways of aromatic degradation, aerobic and anaerobic degradation of aromatic compounds.	
Credit –1 UNIT III	**Microbiome**	**(15)**
	A) Introduction-Microbiome Ecosystem Ecology B) HumanMicrobiomeproject: Scientific background; Initiation of the HMP; The goal of the HMP; Implementation of the National Institute of Health HMP; The International Human Microbiome Consortium (IHMC). C) Healthy Human Microbiome: Typical components and diversity of the microbiome; archaea, viruses, fungi, and other eukaryotes; Geographical variation in the healthy microbiome; Microbiome establishment and early colonization; Hallmarks of health;outlook. D) Human Microbiome at the interface of health and disease: Influences on the microbiota during host life cycles; Disease links and health implications.	
Credit –1 UNIT IV	**Extremophiles and their Applications**	**(15)**
	A) Extremophiles i) Concept ii) Thermophiles – Nucleic acids, Membrane adaptations, Proteins. iii) Psychrophiles – Membrane adaptation, Proteins iv) Acidophiles – Mechanism to tolerate acid and metal and acid toxicity. v) Alkalophiles- Bioenergetics adaptations. B) Extremozymes i) Extremozyme – Characteristics, examples, structure, Biotechnological uses of archea as extremozymes and applications. ii) Biotechnological, applications of extreme proteins from different groups of methanogens. iii) Polyextremophiles – characteristics, examples and uses	

Course Outcomes: Student should be able to :-

1. Comprehend the concepts of microbial ecology.
2. Apply recent trends in ecology for global sustainability.
3. Utilize extremophiles as industrial tools.
4. Imbibe basic concepts of the human microbiome.

References:-

1) R.M.Atlas, R. Bartha (2008) Microbial Ecology: Fundamentals and Applications, 4th Ed. Pearson India Education Services

2) Charles Greday, Nicolas Glansdorff.(2007)Physiology and Biochemistry of Extremophiles, ASM Press.

3) RajendranP,Gunasekaran P. (2011) Microbial Bioremediation, MJP Publishers,Chennai

4) Odum Eugene (2004) Fundamentals of Ecology, Cengage Learning

5) The Human Microbiome : At the Interface of Health and Disease-Ilseung Cho and Martin J. Blaser, 2012, Nature Journal

6) Ecology principle and application by J.I, Chapman and M.J. Reiss, 1992

MAMiT 302: ESSENTIALS OF IMMUNOLOGY

Course Objectives: Student will able to :-

1. Understand various immunotechniques.
2. Study advanced concepts in immunology.
3. Study immunodeficiency diseases.
4. Study cell signaling pathways and concept of apoptosis

Credits=4	**SEMESTER-III** **MAMiT 302: ESSENTIALS OF IMMUNOLOGY**	**No. of hours per unit/ credits**
Credit –I UNIT I	**Cell signaling and Apoptosis**	**(15)**
	A) Cell Signaling 1) Signal receptors in immune system 2) Signal Transduction Pathway- a) JAK-STAT Pathway b) Phosphatidyl Inositol Pathway c) RAS-MAPK Pathway 3) IL 2 Signaling Pathway 4) Chemokine Signaling Pathway B) Apoptosis 1) Molecules involved in apoptotic cell death 2) Mechanism of apoptosis a) Extrinsic Pathway b) FAS signaling pathway c) Intrinsic Pathway	
Credit –1 UNIT II	**MHC complex and experimental systems**	**(15)**
	Major Histocompatibility Complex a) General Organization and Inheritance of the MHC b) Inheritance of MHC haplotypes in inbred mouse strains c) MHC molecules and genes. d) Detailed genetic map of MHC genes. e) Cellular distribution of MHC molecule f) Regulation of MHC expression g) MHC and immune responsiveness. h) Exogenous and endogenous pathways of antigen processing and presentation 1) Experimental Systems- Experimental animal models & cell culture system .	
Credit –1	**Tumor immunology and immunotechniques**	**(15)**

UNIT III		
	1) Immunity to tumors a) Tumor of immune system b) Tumor antigen c) Immune responses to tumor- T cell , antibodies ,NK cell,Macrophages d) Evasion of immune response by tumors e) cancer immunotherapy. 2) Immunotechniques a) Flow Cytometry b) Immunogold labelling for electron microscopy c) Immuno PCR d) Mixed lymphocyte reaction. e) Radioimmunoassay f) Immunoprecipitation	
Credit –1 **UNIT IV**	**Immunodeficiency Disorders**	**(15)**
	1) Primary immunodeficiencies a) Lymphoid immunodeficiencies i) Humoral Deficiencies- XLA, XHM ii) Cell mediated Deficiencies – DiGeorge Syndrome iii)Combined Deficiencies – Severe SCID b) Immunodeficiencies of the myeloid lineage i) Phagocytic Deficiencies- CGD, reduction in neutrophils count c) Complement defects- Defects in C3 component 2)Secondary immunodeficiencies a) Causative factors of secondary immunodeficiency diseases b) AIDS – Target cells infection by HIV, HIV-1 Latency, Factors promoting HIV Provirus, Mechanism of immunodeficiency 3) Treatment of Immunodeficiency Diseases 4) Immunotechniques and their applications, Principle, Procedure, Application, Advantages and disadvantages. iv)	

Course Outcome: Student should able to

1) Understand the concept of immune system and its relation with various microbes.
2) Explain advances in the field of immunodeficiency.
3) Explain about immune response to diseases and tumors.
4) Use techniques and experimental systems required in immunological research.

REFERENCE BOOKS:

1. Cellular and Molecular Immunology – Abul K. Abbas. 2003, 5th Edition
2. Kuby Immunology – Kindt Goldsby and Osborne. 1984, CBS college publication
3. Immunology – Tizard 2005, 2nd edition
4. Immunology – C. Vaman Rao, 2011, 12th edition
5. Essential Immunology – Roitt I.M.
6. Basic and clinical Immunology – Danie P. Stites, John Stobo, H. Fudenberg, 1984 (LOS Altos, Calif, Lange medical publication.

MAMiT 303: PHARMACEUTICAL MICROBIOLOGY

Course Objectives: Student will able to-

1. Understand the recent research on drug discovery and development.
2. Understand the tools and techniques used in antimicrobial testing.
3. Study emerging trends in biopharmaceuticals.
4. Study microbial spoilage of pharmaceutical products

Credits=4	**SEMESTER-III** **MAMiT 303: PHARMACEUTICAL MICROBIOLOGY**	**No. of hours per unit/ credits**
Credit –1 UNIT I	**Drug Discovery and Development**	**(15)**
	A) Introduction i) Contributions and postulates of Paul Ehrlich ii) Significance of terms - lead optimization, candidate selection B) Drug Discovery and Design i) Conventional Process of bioprospecting (medicinal chemistry) ii) Extraction and purification principles, iii) Purification and characterization of bioactive molecules from natural sources iv) Rational Drug Design – Principle (Structure Activity Relationship- SAR) and Tools (applications of High Throughput Screening, Combinatorial Synthesis, Pharmacogenomics) C) Drug Development i) Preclinical Development – Toxicity Testing: Acute, Sub-acute and Chronic. ii) Clinical Development iii) Clinical Trials: Aims, Objectives, Conduct, Phases of Clinical Trials – I,II,III, IV.	
Credit –1 UNIT II	**Antimicrobial Testing Systems**	**(15)**
	A) Introduction: Antimicrobial agents, broad types, therapeutic ratio, MIC and MBC. B) Antimicrobial Susceptibility Testing i) Use of liquid and solid media. ii) Factors affecting susceptibility testing, guidelines issued by CLSI. iii) Diffusion methods – a) Agar Dilution Technique b) Gradient Plate Technique c) E-test	

	d) Kirby Bauer Method e) Stokes Method iv) Susceptibility Testing for – a) Anti-mycobacterial agents. b) Anti-fungal agents. c) Anti-protozoan agents. Anti-viral agents.	
Credit –1 UNIT III	**Biopharmaceuticals**	**(15)**
	A) Introduction: Concept and significance of biopharmaceuticals. B) Regulations and Recommendation i) Regulatory authorities and their role – the FDA. ii) The concept of Pharmacopoeia – USP, EP, BP and IP. C) Drug Formulation Studies i) Drug formulations – carriers and delivery systems. ii) Targeted drug delivery and sustained release. iii) Pharmacokinetics – ADME / Bioavailability studies.	
Credit –1 UNIT IV	**Microbial spoilage of pharmaceutical product, infection risk, contamination control**	**(15)**
	Spoilage- chemical and physicochemical deterioration of pharmaceuticals observable effects of microbial attack on pharmaceutical products B) Pharmaceutical ingredients susceptible to microbial attack i) Therapeutic agents ii)surface active agents iv) Non - ionic surfactants v) Organic polymers vi) Humectants vii) Fats and oils viii) Sweetening, flavoring and colouring agents. ix) Preservatives and disinfectants. C) Factors affecting microbial spoilage ofpharmaceutical products a. Types and size of contaminant inoculum b. Nutritional factors c. Moisture content: water activity (Aw) d. Redox potential e. storage temperature	

Course Outcomes: Student should be able to: -

1. Imbibe the basic concepts of drug development.
2. Perform antimicrobial testing.
3. Comprehend the concept of biopharmaceuticals.
4. Understand pharmaceutical ingredients susceptible to microbial attack

References: -

1. K. Park (2009), 20th Edition Park's Textbook of Preventive and Social Medicine
2. Konrad J. Karczewski, Roxana Daneshjou, Russ B. Altman, 2012 Chapter 7. Pharmacogenomics PLOS
3. Franklin T.J. and Snow G.A., 1975, Biochemistry of Antimicrobial Action, Chapman and Hall, London
4. Gale E.F., Cundliffe E., Reynolds P.E., Richmond M.H. and Waring M.J., 1972, The molecular basis of antibiotic action, John Wiley and Sons, London
5. Goldstein A., Aronow L. and Kalman S.M. 1969, Principles of Drug Action, The Basis of Pharmacology, Harper International Edition, New York
6. Mannfred A. Holliger, 2008, Introduction to Pharmacology, 3rd Edition, CRC Press
7. Kokate C. K., Purohit A.P., Gokhale A.B.2000, Pharmacology, 4th Edition, Nirali Prakashan

MAMiT 304 – FOOD AND DAIRY MICROBIOLOGY

Course Objectives: Student will able to: -

1. Understand the significance of starter culture for in food and dairy industry
2. Study concept of prebiotic and probiotics
3. Understand the techniques used in food preservation
4. Study the Artificial intelligence in food industry and food safety and standards

Credits=4	**SEMESTER-III** **MAMiT 304: FOOD AND DAIRY MICROBIOLOGY**	**No. of hours per unit/ credits**
Credit –I UNIT I	**Microbiology of Starter Cultures and fermented dairy products**	**(15)**
	a) Introduction and annual utilization of starter cultures; History and taxonomy of b) Starter cultures; Classification of starter organisms: Starter types: single, mixed and multiple strain starter cultures; c) Propagation and preservation of starter cultures; commercial starter preparations: concentrated and super concentrated starters d) Metabolism of starter Organisms: biochemical characterization of lactic acid bacteria; carbohydrates, citrate and protein metabolism of starter cultures e) Role of starter cultures in the preparation of various fermented milk, Microbiology iv) of fermented milk products: their nutritional and therapeutic significance.	
Credit –1 UNIT II	**Probiotics and functional food**	**(15)**
	a) Introduction and history of Probiotics, safety of probiotic microorganisms,legal status ofprobiotics Characteristics of Probiotics for selection. b) Tolerance to additives,stability during storage, stability during passage to intestinal sites, Role of probiotics in health and disease, minimum effective dose, maintenance of probiotic microorganisms. c) Prebiotics: concept, definition,criteria, types and sources of prebiotics, prebiotics and gut microflora, Prebiotics and health benefits: prebiotics in foods d) Health benefits of functional fermented dairy products: such as	

	dahi, lassi, yoghurt, kefir, cheese, koumiss, Yakult, fermented whey drinks, and dairy based cereal foods, soy based yoghurt containing probiotics.	
Credit –1 UNIT III	**Microbiology in Food**	**(15)**
	A) Microorganism in food spoilage: i) Types of foods and their spoilage ii) Microbial, biochemical aspect of food spoilage iii) Physiology of food spoilage organisms : Importance, Response of microbes, future prospectus. C) Food Preservation i) Control of spoilage: By physical removal, heat, low temperature, reduced aw,low pH, organic acids, modified atmosphere, anti - microbial preservatives, irradiation, canning. ii) Control by combination of methods (Hurdle concept) iii) Novel emerging techniques of preservation – Bacteriocin - Introduction, types, mode of x) action, applications.	
Credit –1 UNIT IV	**UNIT IV: Artificial intelligence in food industry**	**(15)**
	I) Artificial intelligence in food industry and food safety and standards A) Introduction B) Applications of artificial intelligence in food industry II) Quality control and Regulations of food industry: Microbiological quality control of milk and milk products: ISI standards, FAO/WHO regulations, FDA regulations and APHA/IDF regulations. Principles of HACCP in Food industries, Quality Manuals and documentations for different products, Basic GMP in the v) industry.	

Course Outcomes: Student should be able to :-

1.Understand the significance of starter culture for in food and dairy industr.

2. Apply the techniques in food preservation

3. Understand the basics of artificial intelligence in food industry .

4. Understand the concepts of food safety and regulations in food industry.

References:-

1. K. Vijaya Ramesh, 2007, Food Microbiology, MJP Publishers, Chennai
2. Swaminathan M, 1974, Essentials of Food and Nutrition, 2nd Edition, Ganesh and Co. –
3. Modi H.A. 2009, Dairy Microbiology, Pointer Publishers, India
4. J.S. Yadav, Grover S., Batish V.K, 1993, Comprehensive Dairy Microbiology, Metropolitan Book Cooperative Pvt. Ltd.
5. Frazier W, Westoff D. 2013 Food Microbiology, 5th Edition, Tata McGraw Hill Education

MAMiP 305
PRACTICAL COURSE – III: LAB – V

Course Objectives: Student will be able to:-

1) Study the different aspects of microbial ecology like biofilm, biodegradation.
2) Understand the mechanisms employed by extremophiles for survival.
3) Employ various techniques involved in the branch of immunology.
4) Understand the pharmaceutical microbiology

Credits-4	**SEMESTER-III** **MAMiP 305: PRACTICAL COURSE – III: LAB - V**	**No. of hours per unit/60 Credits**
Credit-2 UNIT I	**Microbial Ecology**	
	A] Microbial Ecology 1) Adhesion of microorganisms to surface by dip slide method. 2) Study of siderophore producing microorganisms. 3) Isolation of petroleum degrading bacteria and determination of degradation rate. 4) Determination of rate of degradation of dye using microbial isolate. B] Extremophiles 5) Isolation of thermophiles from compost heap. 6) Screening of alkaliphilic bacteria from soil/water. 7) Isolation and enrichment of psychrophiles. 8) Screening of halophilic and halotolerant microorganisms. C]Human Microbiome 10) Qualitative analysis of the hand microbiome by suitable method. 11) Isolation of etiological agent of dental caries.	
Credit –2 UNIT II	**Essentials of Immunology**	
	Essentials of Immunology 1) Determination of antibody titer by Ouchterlony double diffusion test. 2)Demonstration of SDS-PAGE technique 3)ELISA- Detection of antigen/ antibody by Sandwitch ELISA. 4)Rocket immunoelectrophoresis 5) Radial Immunodiffusion test 6) Purification of H antigen from *S. typhi* 7)Estimation of alkaline phosphatase from patients serum 8)Purification of Antibodies using ammonium sulphate precipitation & column chromatography.	

Course Outcome: Student should be able to:-

1. Understand the different aspects of microbial ecology like biofilm, biodegradation.
2. Understand the mechanisms employed by extremophiles for survival.
3. Understand techniques involved in the branch of immunology.
4. Understand the pharmaceutical analysis and testing

MAMiP 306: PRACTICAL COURSE – III: LAB – VI

UNIT – I

Course Objectives: Students will be able to:-

1. Study the different aspects of microbial ecology like biofilm, and biodegradation,
2. Understand the mechanisms employed by extremophiles for survival.
3. Understand to use various techniques involved in the branch of immunology
4. Study the different facets of pharmaceutical microbiology by practical analysis and testing.

Credits-4	**SEMESTER-III** **MAMiP 306: PRACTICAL COURSE – III: LAB - VI**	**No. of hours per unit/60 credits**
Credit-2 **UNIT I**	Pharmaceutical Microbiology	
	1) Determination of Epidemiological Ratios: a) Human Development Index, b) Mortality Ratio, c) Morbidity Ratio. 2) Extraction of bioactive ingredients from plant and its activity fraction. 3) Determination of Minimum Inhibitory Concentration (MIC) of drug. 4) Estimation of antimicrobial activity using CLSI. 5) Determination of phenol coefficient. 6) Study of antimicrobial activity of spices. 7) Determination of microbial load of non-sterile products – ointments, capsules. 8) Determination of drug sensitivity of Streptococcus mutans	
Credit-2 **UNIT II**	Essentials of Bioinformatics	
	1) Study of network IP. 2) Connecting computers in a Local Area Network (LAN). 3) Searching sequence databases by BLAST – a) BLASTn, b) BLASTp.	

Course Outcomes: Students should be able to:-

1. Perform analysis and testing of pharmaceutical products.
2. Perform MIC of drug
3. Perform independently microbial load of non-sterile product testing.
4. Understand the database by BLAST.

References:-

1.R. M. Atlas,R. Bartha(2008) Microbial Ecology: Fundamentals and Applications, 4 th Ed., Pearson India Education Services.

2. Sandhya Mitra – Genetic Engineering: Principles and Practice, McGrawHill Education (India) Pvt. Ltd.

3. Kokate C. K., Purohit A.P., Gokhale A.B. (2000)Pharmacology,

4 th Edition, Nirali Prakashan.

SEMESTER IV

MAMiT 401 – INDUSTRIAL MICROBIOLOGY

Learning Objectives: Student will able to:-
1. Understandthe basic concepts of fermentation technology.
2. Study the significance of microbial sensors.
3.Study economical aspects of solid state fermentation.
4. Understand with various concepts related to intellectual property.

Credits=4	**SEMESTER-IV** **MAMiT 401 – INDUSTRIAL MICROBIOLOGY**	**No. of hours per unit/ credits**
Credit –I UNIT I	**Fermentation Technology**	**(15)**
	A) Concept of Biosensors a) Cell Immobilization - Introduction, Immobilized cell system – i) Surface attachment of cells. ii)Entrapment within porous matrices. iii)Containment behind a barrier. iv)Self-aggregation of cells b) Design of immobilized cell reactors – i) Mass transport phenomena in immobilized cell system. ii)Reaction and diffusion in immobilized cell system iii)Bioreactor design iv)Physiology of immobilized microbial cells. B) Types of electrochemical microbial sensors i)Optical biosensors. ii)Other types.	
Credit –1 UNIT II	**Microbial Biosensors**	**(15)**
	C) Concept of Biosensors c) Cell Immobilization - Introduction, Immobilized cell system – j) Surface attachment of cells. ii)Entrapment within porous matrices. iii)Containment behind a barrier. iv)Self-aggregation of cells d) Design of immobilized cell reactors – j) Mass transport phenomena in immobilized cell system. ii)Reaction and diffusion in immobilized cell system iii)Bioreactor design iv)Physiology of immobilized microbial cells. D) Types of electrochemical microbial sensors	

	i)Optical biosensors. ii)Other types.	
Credit –1 UNIT III	**Solid State Fermentation and Fermentation Economics**	**(15)**
	A) Solid state fermentation (SSF) :- Introduction, comparison of SSF and submerged fermentation, Advantages, disadvantages, problems, types, Factors affecting, fermenter design for SSF, Koji manufacturing process, industrial application of SSF, amylase production –case study. B]Fermentation economics:- Introduction, economic objectives. Various aspects influencing fermentation economicsStrain improvement, High yielding strain, Market potential, fermentation media and raw material, fermentation equipment's, recovery cost, water uses and recycling, effluent treatment.	
Credit –1 UNIT IV	**UNIT IV: IPR and Patenting**	**(15)**
	A)Intellectual Property Rights Introduction and concept of IPR, the World Intellectual Property Organization (WIPO), Fields of intellectual property protection, General introduction to patents, copyrights and trademarks. A) Patents: i)Introduction, conditions of patentability, drafting and filing a patent, examination of a patent application, infringement, exploitation of the patented invention, compulsory licenses. Utility models ii)Indian Patent Act C]Intellectual Property and Bioethics: Introduction, general principles and key aspects.	

Course Outcomes: Student should be able to:-

1. Use and manipulate different types of fermenter and fermentation process
2. Understand designing of immobilized cell reactors
3. Understand the technique of solid state fermentation for laboratory production of metabolites.
4. Understand bioethical concepts and fundamentals for social welfare.

References:-

1.Mansi E. L. Fermentation Microbiology and Biotechnology, 2011, 2nd Edition, CRC Press
2.Patil S.C. Industrial Microbiology, 2010, S. Chand and Company
3.Casida J.R. Industrial Microbiology, 2016, New Age International Pvt. Ltd.
4.Peppler H.J., Pearlman D. Microbial Technology, 1979, 2nd Edition, Academic Press
5.Stanbury P.P., Whitekar A., Hall S.J. 2008, Principles of Fermentation Technology, Elsevier
6.Intellectual Property Rights in India, Shodhganga, 2015,Chapter 2
7.WIPO Intellectual Property Handbook, 2004, 2nd Edition, Chapters 1 and 2
8.Intellectual Property and Bioethics: An Overview, 2021, WIPO Booklet

MAMiT 402– MICROBIOLOGICAL QUALITY CONTROL AND ASSURANCE

Course Objectives : Student will be able to:

1. Understand specific requirements for production of different products in the pharmaceutical industry.
2. Study the techniques and tools for facility and instrument qualification.
3. Study the concept of clean room technology and culture maintenance and disposal.
4. Understand the essentials of analytical techniques employed in the pharmaceutical industry.

Credits=4	**SEMESTER-IV** **MAMiT 402– MICROBIOLOGICAL QUALITY CONTROL AND ASSURANCE**	**No. of hours per unit/ credits**
Credit –I UNIT I	**Pharmaceutical Industry**	**(15)**
	A]Schedule M:- Part I-A: Specific Requirements for Manufacture of Sterile Products, Parenteral Preparations and Sterile Ophthalmic Preparations. Part I-B: Specific Requirements for Manufacture of Oral Solid Dosage Forms (Tablets and Capsules). Part I-C:Specific Requirements for Manufacture of Oral Liquids(Syrups, Elixirs, Emulsions and Suspensions). Part I-D: Specific Requirements for Manufacture of Topical products i.e. External Preparations(Creams, Ointments, Pastes, Mulsions, Lotions, Solutions, Dusting Powders and Identical Products). Part I-E: Specific Requirements for Manufacture of Metered Dose-Inhalers (MDI). Part I-F: Specific Requirements of Premises, Plant and Materials for Manufacture of Active Pharmaceutical Ingredients (Bulk Drugs)	
Credit –1 UNIT II	**Facility and Instrument Qualification**	**(15)**
	A] Introduction:- URS, IQ, OQ, PQ. B]HVAC Qualification:- Heating Ventilation Air Conditioning System, Constituents of the System– Temperature, Relative Humidity, Air Velocity, Differential Pressure and Room to Room Air Balancing, HEPA Filtration, LAF, Viable Count. Utility Qualification:- C)Purified Water System and Pharmaceutical Air Monitoring. D)Instrument Qualification:- 1)Autoclave, 2) Dry heat sterilizer, 3)Incubator and 4) Laminar Air Flow Cabinet.	
Credit –1 UNIT III	**Maintenance of Clean Room & Microbiological Laboratory**	**(15)**

	A) Facility Requirements:-Introduction and guidelines. B) Gowning Requirements:-Introduction and guidelines. C) Disinfectant Qualification:- Introduction, Types of Disinfectants, Disinfectant Efficacy Testing. D)Clean-in Place(CIP) and Sterilize-in Place(SIP):- Introduction, Principle, Protocol and Applications of CIP and SIP. E)Culture Maintenance:- Reference cultures used in the pharmaceutical industry,maintenance. F] Disposal Systems:- Disposal protocols and systems for cultures and media.	
Credit –1 UNIT IV	**UNIT IV: Essentials of Analytical Techniques in Pharma Industry**	**(15)**
	A) Media Preparation, Sterilization and Growth Promotion. Guidelines for a) Media Preparation, b) Sterilization and c) Growth Promotion. B) Environment Monitoring. Introduction, Need for EM, Procedure and Significance. C] Endotoxin Testing Introduction, Gel Clot Method, Kinetic Assays, Medical Devices. D] Antibiotic / Vitamin Assay. General Information, Equipment, Test Organism, Inoculum preparation And Standardization, Antibiotic/Vitamin Standard and Sample Solution Preparation, Growth Media and Additional Test Solutions, Potency Testing –Plate Method and Tube Method. Calculations. E] Bioburden Estimation of Medical Devices. Definition of Bioburden, FDA Guidelines, Significance. F] Microbiological Examination of Non- Sterile Products. Product storage and handling,gowning requirements, Growth promotion and inhibitory properties of the media Suitability of the test method, test procedure, interpretation of the results. G] Preservating Efficacy Testing(PET). Media, Growth promotion of the media, suitability of the counting method in the presence of product, test organisms, preparation of the inoculum, procedure and interpretation.	

Course Outcomes: Student should be able to:-

1. Understand specific requirements for production of different products in the pharmaceutical industry.
2. Comprehend the techniques and tools for facility and instrument qualification.
3. Imbibe the concept of clean room technology and culture maintenance and disposal.
4. Understand the use of various analytical techniques employed in the pharmaceutical industry.

References:-

1.Pharmaceutical Microbiology Manual (PMM), United States Food and Drug Administration (USFDA), ORA.007, Version 1.2, 2014.
2.Indian Pharmacopoeia (IP), Volume II (P-Z, Reference Spectra and Appendices), Ministry of Health and Family Welfare, Government of India, 1996.
3.Manohar A. Potdar, Pharmaceutical Quality Assurance, 2nd Edition, NiraliPrakashan, 2007.
4.Baird R.M., Hodges N.A.,DenyerS.P.,Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices,CRC press, 2000

MAMiT. 403: GENE TECHNOLOGY AND GENOMICS

Course Objectives: Student will be able to:-

1. Study the basic knowledge on gene technology
2. Understand with the recent research in the sphere of gene technology.
3. Understand the tools and techniques used in genetic engineering.
4. Study about emerging trends in gene technology

Credits=4	**SEMESTER-IV** **MAMiT 403– GENE TECHNOLOGY AND GENOMICS**	**No. of hours per unit/ credits**
Credit –I UNIT I	**DNA Libraries**	**(15)**
	A) Introduction and types- Genomic and cDNA library. B)Preparation of Genomic Library- Isolation of genomic DNA, generation of suitable sized fragments, cloning in suitable vectorsystems, and transformation in suitable host. C)Preparation of cDNA library- Isolation of mRNA, preparation of cDNA fragments, cloning in suitable vector systems, and transformation in suitable host. D)Screening of Libraries-Criteria to identify particular gene from gene library – 1)DNA sequencing 2)Expression of particular protein with immunological epitope 3.Enzymatic activity	
Credit –1 UNIT II	**Directed Mutagenesis and Protein Engineering**	**(15)**
	A) Directed Mutagenesis: Oligonucleotide directed mutagenesis with M-16 phage, PCR-amplified oligonucleotidedirected mutagenesis, error-prone PCR, Random insertion and deletion mutagenesis,selection of mutant peptide – phage display and cell surface display B) Protein Engineering: Adding disulfide bonds, changing aspargine to other amino acids, reducing number offree sulfhydryl residues, increasing enzymatic activity, modifying metal cofactor requirement, decreasing protein sensitivity, modifying protein sensitivity increasing enzyme stability and specificity, altering multiple properties.	
Credit –1 UNIT III	**Genetic Engineering in Plants and Animals**	**(15)**
	Plants i) Plant transformation with Ti and Ri plasmid.	

	ii) Ti plasmid derived vector systems. iii) Physical methods for transformation. iv) Chloroplast engineering animals i) Gene transfer vectors ii) Transfection – a) Physical, b) Chemical. iii) Production of transgenic mice, Retroviral vector method, DNA microinjection method Applications of transgenic mice, Transgenic Disease Models: Alzheimer's disease, Duchenne muscular dystrophy, Transgenic mice as test system	
Credit –1 UNIT IV	**UNIT IV: Recent Trends in Gene Technology**	**(15)**
	A]Genomics- Concept, Introduction, Comparative genomics of bacteria B] Proteomics- Concept, Introduction, Expression analysis and characterization of proteins C] CRISPR / Cas9 in Genome Editing- Concept, Introduction, Applications.	

Course Outcomes: Student should able to:-

1. Access various genomic libraries
2. Comprehend recent trends in protein engineering.
3. Understand to utilize the applications of genetic engineering to industrial use.
4. Understand the significance of gene technology for biological research.

References:-

1.Sandhya Mitra –Genetic Engineering: Principles and Practice, 1996, 1st edition, McGraw Hill Education (India) Pvt. Ltd

2.Glick, Pasternak, Patten –Molecular Biotechnology: Principles and Applications of Recombinant DNA Technology 2010, 4th Edition, ASM Press

3.S.B. Primrose, R. M. Twyman – Principles of Gene Manipulation and Genomics 7th Edition) Blackwell Publishing, cornwall UK

4.Hartl and Jones – Genetics: Daniel L. Hartl, E. W. Jones, Analysis of Genes and Genomes 2009, 8th Edition, Jones and Bartlett Learning, Canada

5.Review Article: CRISPR/CAS 9 in genome editing by Haifeng Wang, Marie La Bussa, Lei S. Qi 2016, Annual review of biochemistry, Vol–85

6.Recent trends progress in CRISPR technology by Yue Mei, Yan Wang, 2016 – Journal of Genetics and Genomics – Berjiling

MAMiT 404 ADVANCED BIOINFORMATICS

Course Objectives: Student will be able to:-

1. Studythe concepts regarding basics of bioinformatics
2. Understand the Sequence alignment and phylogenetic analysis
3. Stduy the tools for sequence alignment
4. Understand the essentials of structural bioinformatics and gene annotation

Credits=4	**SEMESTER-IV** **MAMiT 404– ADVANCED BIOINFORMATICS**	**No. of hours per unit/ credits**
Credit –I UNIT I	**Introduction to Bioinformatics**	**(15)**
	i) Introduction, History of Bioinformatics, Applications. ii) Major databases in bioinformatics a. Nucleic acid databases (Gene Bank, DDBJ, EMBL). b. Protein Databases (Primary, Secondary and Composite). c. Specialized Genome Databases. d. Structural Classification Databases e. Structural Databases(PDB). iii) Data management and analysis iv) Molecular biology and bioinformatics v) Information search and data retrieval	
Credit –1 UNIT II	**Directed Mutagenesis and Protein Engineering**	**(15)**
	i) Introduction, ii) Alignment of pairs of sequence iii) Alignment of multiple sequences iv) Phylogenetic analysis, Definition and description of phylogenetic trees and various types of trees, Method of construction of Phylogenetic trees[distance -based method (UPGMA, NJ), Maximum Parsimony and Maximum Likelihood method].	
Credit –1 UNIT III	**Tools for similarity search and sequence alignment**	**(15)**
	i) Working with FASTA ii) Working with BLAST iv) Filtering and gapped BLAST iv) FASTA and BLAST algorithm comparison v) Other programs	

Credit –1 UNIT IV	**UNIT IV: Structural Bioinformatics and Gene annotation**	**(15)**
	i) Introduction to Gene Annotation ii) Protein structure visualization and classification iii)Protein structure databases and Introduction to visualization databases and tools iv) Protein structure alignment v) Protein classification approaches	

Course Outcomes: Student should be able to:-

1. Understand the concepts regarding basics of bioinformatics
2. Understand the Sequence alignment and phylogenetic analysis
3. Understand the tools for sequence alignment
4. Understand the essentials of structural bioinformatics and gene annotation

Reference books:

1. Rastogi S.C. Bioinformatics: Methods And Applications: Genomics, Proteomics And Drug Discovery, 2013, 4th edition, Phi publication
2. C. Stan Tsai, Computational Biochemistry, John Wiley and Sons
3. V.Rajaraman, Fundamentals of Computers, Phi Learning, ISBN:8120321758, 2001
4. Tanenbaum Andrew S, Computer Networks, 2003, 4th Edition, Prentice Hall PTR, ISBN:8120321758
5. Friesner Richard A. Computational Methods for Protein Folding: advances in Chemical Physics Volume 120 Kindle Edition. Publisher: New York, John Wiley and Sons. 2002. ISBN: 0471209554-
6. 5.. Branden ,Tooze John. Introduction to Protein Structure. New York, Garland Publishing Inc. 1999. ISBN: 0815323050 –

MAMiP 405 PRACTICAL COURSE – IV: LAB VII

Course Objectives: Student will be able to

1. Study the different components of fermentation technology and microbial bionsensors.
2. Study of solid state fermentation and its applications.
3. Study the various facets of intellectual property.
4. Study analytical techniques employed in the microbiological quality control.

Credits=4	**SEMESTER-III** **MAMiP405: PRACTICAL COURSE – IV: LAB VII**	**No. of hours per unit/60 credits**
Credit –2 **UNIT I**	**Microbial Ecology**	
	A)Fermentation Technology and Biosensors 1.Determination of blood glucose by glucometer. 2.Laboratory production of alkaline protease by solid state fermentation using bacteria. 3.Protein Assay by tyrosine curve. 4.Laboratory production of citric acid by solid state fermentation using fungi and its estimation. 5.Financial survey of fermentation economics of small-scale Company B) Intellectual Property Group Discussion on: a) Patent and Copyright, b) Bioethics	
Credit –2 **UNIT II**	**Essentials of Immunology**	
	A) Microbiological Quality Control and Management 1) Determination of bioburden on textile material by AATCC 101-2004 method. 2) Determination of Thermal Death Point (TDP) and Thermal Death Time (TDT) of microorganisms. 3) Evaluation of sanitary status of eatery by swab technique. 4) In-house determination of aerobic count of microbial load by settle plate technique. 5) Sterility testing of autoclave using Bacillus stearothermophilus. 6) Determination of efficacy of isopropyl alcohol. 7) Preservative Efficacy Testing.	

	8) Instrument Qualification of: a) Incubator, b) Hot air oven. 9)Detection of leaky substances from bacterial cells.	

Course Outcome: Student should be able to

1. Understand the different components of fermentation technology and microbial bionsensors.
2. Understand solid state fermentation and its applications.
3. Understand the various facets of intellectual property.
4. Understand analytical techniques employed in the microbiological quality control.

MAMiP 406 PRACTICAL COURSE – IV: LAB -VIII

Course Objectives: Student will be able to:-

1. Study isolation of plasmid by chemical method.
2. Study analytical techniques employed in the microbiological quality control.
3. Study biological data using tools and techniques of bioinformatics.
4. Study experiments related to food and dairy microbiology.

Credits=4	**SEMESTER-III** **MAMiP406: PRACTICAL COURSE – IV: LAB VII**	**No. of hours per unit/60 credits**
Credit-2 UNIT I	**Gene technology and genomics**	
	A)Gene technology and genomics 1) DNA amplification by PCR. 2) In-vitro seedling growth and multiplication of carrot. 3) Isolation of plasmid by chemical method. 4) Plasmid curing. 5) Isolation of lysozyme from egg white. 6) Preparation of protoplast using lysozyme and protoplast fusion. 7) Study of bacterial transformation. 8) Demonstration of Southern Blotting. B)Bioinformatics 9) Determination and visualization of protein structure by Rasmol 10) Construction of phylogenetic tree by MEGA. 11) Sequence analysis by Multiple Sequence Alignment.	
Credit –2 UNIT II	**Essentials of Immunology**	
	A]Food and Dairy Microbiology Estimation of antioxidants by spectrophotometric method. Estimation of antinutritional factors (tannic/phytic acid). Detection of food adulteration. Estimation of sodium benzoate from food. Detection of afla-toxins from food. Detection of lactic acid from curd. Estimation of beta-amylase from sweet potatoes. Estimation of pectin from plant material.	

Course Outcomes: Students should be able to:-

1. Perform isolation of plasmid by chemical method.
2. Perform analytical techniques employed in the microbiological quality control.
3. Analyze biological data using tools and techniques of bioinformatics.
4. Perform experiments related to food and dairy microbiology.

References:-

1.Peppler H.J., Pearlman D. (1979) Microbial Technology 2nd Edition, Academic Press

2.Pharmaceutical Microbiology Manual (PMM), 2014, United States Food and Drug Administration (USFDA), ORA.007, Version 1.2,

3.Manual of Methods of Analysis of Foods – Microbiological Testing, 2012, – Food, Safety and Standards Authority of India, Ministry of Health and Family Welfare, Government of India, New Delhi

4.Friesner Richard A. Computational Methods for Protein Folding: advances in Chemical Physics Volume 120 Kindle Edition. Publisher: New York, John Wiley & Sons.2002.ISBN:0471209554