Progressive Education Society's

Modern College of Arts, Science and Commerce (Autonomous)

Ganeshkhind, Pune 411016

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Structure of the M. Sc. Degree course in Microbiology

Choice Based Credit System

Syllabus for M. Sc. Second Year

To be implemented from 2023

M. Sc. Microbiology

Semester III

Course Type	Course Code	Course Name	Credit
Core Compulsory Theory Paper	**23-MBCT-231**	Immunology	4
	23-MBCT-232	Molecular Biology	4
	23-MBCT-233	Clinical Microbiology	4
Core Compulsory Practical paper	**23-MBCP-234**	Practicals Based on Compulsory theory credits	4
Choice Based Optional Papers	**23-MBET-235**	Cell Culture techniques	2
	23-MBEP-235	Practicals Based on Cell Culture techniques	2
	OR		
	23-MBET-236	Experimental Design and Quantitative approach for Biologist	2
	23-MBEP-236	Practicals Based on Experimental Design and Quantitative approach for Biologist	2
	OR		
	23-MBET-237	Microbial Virus Technology	2
	23-MBEP-237	Practicals Based on Clinical Microbiology and Microbial Virus Technology	2

Semester IV

Course Type	Course Code	Course Name	Credit
Core Compulsory Theory Paper	**23-MBCT-241**	Pharmaceutical Microbiology	4
	23-MBCT-242	Microbial Technology	4
Core Compulsory Practical paper	**23-MBCT-243**	Dissertation	4

Any TWO Choice Based Optional Papers	**23-MBET-244**	Quality Assurance and Validation in Pharmaceutical Industry and Development of Anti-infectives	2
	23-MBEP-244	Practicals based on quality assurance and validation in pharmaceutical industry and development of anti-infectives	2
	OR		
	23-MBET-245	Advances in Microbial Technology	2
	23-MBEP-245	Practicals based on Advances in Microbial Technology	2
	OR		
	23-MBET-246	Industrial Waste Water Treatment and Industrial Production of vaccines	2
	23-MBEP-246	Practicals based on Industrial Waste Water Treatment and Industrial Production of vaccines	2
	OR		
	23-MBET-247	Bioethics, Biosafety, Quality control and Quality Assurance	2
	23-MBEP-247	Practical's based on Bioethics, Biosafety, Quality control and Quality Assurance	2

Extra credit Courses for M. Sc.

With Reference to circulars by Savitribai Phule Pune University (Ref: BCUD/76, Ref: BCUD/77, Ref: Circular No. 344/2020), extra credit courses viz. Cyber security courses of 4 credits, Human Rights Education programme of 2 credits, Introduction to constitution of 2 credits have been incorporated in the syllabi of Post Graduate courses.

Regular students can take extra credit courses from their own department or from other departments. The extra credit courses opted and specified by the students and grades obtained for these courses will be noted on their grade sheets.

Course Code	Course Name
22-192	Cyber security Module-I
22-292	Cyber security Module-II
22-191	Human Rights Module-I
22-291	Human Rights Module-II
23-392	Cyber security Module-III
23-492	Cyber security Module-IV
23-394	Skill Development Module-I
23-494	Skill Development Module-II
23-395	Introduction to Constitution

Semester III

23-MBCT-231: Immunology

Core Compulsory Theory Paper

[4 Credits; 60 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:

Students will be able to:

CO1: Explain structure and function of cell receptors.

CO2: Explain the mechanism of self-tolerance and clonal deletion.

CO3: Describe the importance of use of experimental animals.

CO4: Describe the approaches in cancer immunotherapy.

Unit	Title and Contents	Lectures
I	**Cell surface molecules and receptors** i. Definition, general Structure and mechanism (dimerization and rotation), components of signal transduction (extracellular signaling molecule, receptor proteins, intracellular signaling proteins and target proteins) ii. Adhesion molecules in immune activation**,** structure and functionof B Cell Receptor, TCR-CD3 complex, Toll-like receptors, Cytokine receptors, G-protein coupled receptors iii. Signal transduction pathways: IL-2 pathway (JAK/STAT, Ras /MAP Kinase Pathways, TCR-CD3 activation pathway)	15
II	**Regulation of Immune response** i. Negative Regulation-Immunological tolerance, Mechanisms of tolerance induction (related experimentation using transgenic animals), T cell mediated suppression of immune response **i.** Regulation of immune responses by antigen, **ii.** Antigen-antibody complexes, Network theory and its experimental evidence iv. Cytokine mediated cross regulation of TH subsets (TH1-TH2) v. Regulation of complement system – Classical and alternative pathway vi. Biological Response Modifiers for cancer therapy and autoimmune disorders	15

III	**Experimental Immunology** i. *In vitro* systems –Quantification of cytokines (ELISPOT assay), functional assays for phagocytes and cytokines (cytotoxicity and growth assays) ii. *In vivo* systems – Experimental animals in immunology research (Inbred animal strains, Knockout mice, transgenic animals), Animal models for autoimmunity and AIDS	15
IV	**Tumor Immunology** i. Cellular transformations during neoplastic growth, Classification of tumors based on histological, Tumors of lymphoid system (lymphoma, myeloma, Hodgkin's disease) i. Escape mechanisms of tumor from host defense, Host immune response to tumor – Effecter mechanisms, Immuno- surveillance theory ii. Diagnosis of tumors – biochemical and immunological tumor markers iv. Approaches in cancer immunotherapy: Immune adjuvant and tumor vaccine therapy	15

Suggested references 23-MBCT-231 Immunology Semester III	
Unit I	**Cell surface molecules and receptors** 1. Austyn J. M. and Wood K. J. (1993). Principles of Molecular and CellularImmunology. First edition Oxford University Press, New York. 2. Barret J. T. (1983). Text Book of Immunology. Fourth edition. Saint Louis,Mosby, London. 3. Boyd W. C. (1966). Fundamentals of Immunology, Interscience Publishers, NewYork. 4. Gangal S. and Sontakke S. (2013). Textbook of Basic and Clinical Immunology. University Press, India. 5. Garcia K. C. and Adams E. J. (2005). How the T Cell Receptor Sees Antigen-A Structural view of Cell 122(3): 333–336. 6. Hafler D. A. (2007). Cytokines and interventional immunology, NatureReviews, Immunology. 7(6): 423-423. 7. Kindt T. J., Osborne B. A. and Goldsby R. A. (2006). Kuby Immunology, Sixth edition, W. H. Freeman & Co. 8. Yoshimura A., Naka T. and Kubo M. (2007). SOCS proteins, cytokine signalingand immune regulation. Nature Reviews, Immunology, 7(6): 454-465

Unit II	**Regulation of Immune response** 1. Abbas A. K. and Lichtman A. H. (2004). Basic Immunology. Functions and Disorders of Immune System. Second edition. Elsevier Inc. 2. Carroll M. C. (2004). The complement system in regulation of adaptive immunity. Nature Immunology. 5(10): 981-986. 3. Kindt T. J., Osborne B. A. and Goldsby R. A. (2006). Kuby Immunology. Sixth edition. W. H. Freeman & Co 4. Patwardhan B., Gautam M. and Diwanay S. (2006). Botanical immunomodulators and chemoprotectants in cancer therapy. In Drug Discovery and Development Volume I: Drug Discovery. Ed. Chorghade Mukund S. Wiley- Interscience, John Wiley and SonsInc. USA. 405-424. 5. Roitt I. M. (1984) Essentials of Immunology. P. G. Publishers Pvt. Ltd., New Delhi. 6. Roitt I. M. 1988. Essentials of Immunology. ELBS, London. 7. Yoshimura A., Naka T. and Kubo M. (2007). SOCS proteins, cytokine signaling and immune regulation. Nature Reviews. Immunology. 7(6): 454- 465
Unit III	**Experimental Immunology** 1. Gangal S. and Sontakke S. (2013). Textbook of Basic and Clinical Immunology. University Press, India. 2. House R. V. (1998). Therapeutic Manipulation of Cytokines, Biotechnology andSafety Assessment. Second edition. Taylor & Francis. 81-105. 3. Kindt T. J., Osborne B. A. and Goldsby R. A. (2006). Kuby Immunology. Sixth edition. H. Freeman and Co. 4. Mather J. P. and Roberts P. E. (1998). Introduction to Cell and Tissue Culture Theoryand Technique. Plenum Publishing Corporation, New York. 5. Roitt I., Brostoff J. and Male D. (1993). Immunology. Sixth edition. Mosby & Co.London. 6. Talwar G. P. (1983). Handbook of Immunology. Vikas Publishing Pvt. Ltd.New Delhi. 7. Paul W. E. (2003). Fundamental Immunology. 5th Ed. Lippincott. Williams and Wilkins Publishers.
Unit IV	**Tumor Immunology** 1. Bendelac A., Savage P. B. and Teyton L. (2007). The Biology of NKT Cells.Annu. Rev. Immunol. 25: 297–336. 2. Chatterjee C. C. (1992). Human Physiology Tenth Edition Vol. 1 and 2.Medical AlliedAgency, Calcutta. 3. Diwanay S., Gautam M. and Patwardhan B. (2004). Cytoprotection and Immunomodulation in Cancer Therapy. Current Medicinal Chemistry - Anti- Cancer Agents. 4(6): 479-490. 4. Guyton A. C. and Hall J. E. (1996). Text Book of Medical Physiology. Goel Book Agency, Bangalore. 5. Leen A. M., Rooney C. M. and Foster A. E. (2007). Improving T cell therapy for cancer. Annu Rev. Immunol. 25 (1): 243–265. 6. Malati T. (2007). Tumor Markers: An Overview, Indian Journal of Clinical Biochemistry 22(2): 17-31. 7. Patwardhan B. Gautam M. and Diwanay S. (2006). Botanical Immunomodulators and

	Chemoprotectants in Cancer Therapy. In Drug discovery and development Volume I: Drug Discovery. Ed. Chorghade Mukund S. Wiley- Interscience, John Wiley and SonsInc. USA. 405-424. Stuhler G. and Walden P. 2002. Cancer Immune Therapy - Current and Future Strategies. Wiley-VCH.

Semester III

23-MBCT-232: Molecular Biology

Core Compulsory Theory Paper

[4 Credits; 60 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:
Students will be able to:

CO1: Describe the concept of gene variation, role of Prokaryotic and eukaryotic SNPs and explain methods/tools for detection of SNPs.

CO2: Explain approaches to produce GMOs and their applications in different fields

CO3: Explain families of transposable elements, their origins, significance and the process of transposition

CO4: Describe various steps involved in Proteomic studies and applications of proteomics

Unit	Title and Contents	Lectures
I	**1. Genomics** a) Gene sequencing, conserved genes, finding base sequences which form genes b) Many proteins from one gene, alternative gene expression: DNA imprinting and Epigenetics. c) Genomic variation -SNPs, SNPS and diseases, SNPS detection and medical therapies. Eukaryotic and prokaryotic SNPs d) Role of genomic variation in aging, Recognition of trades offs associated with genomic variation.	15
II	**2. Genetically modified plants and animals** a) Genetically modified organisms-social and ethical issues b) Gene augmentation and gene therapy c) Applications in medicine – prevention, early detection and cure of diseases d) Applications of transgenic plants and animals - advantages and disadvantages	15
III	**3. Mobile DNA elements** a) Transposable elements in bacteria, IS elements, composite transposons, Integrons. b) Replicative, non-replicative transposons, and Mu transposition c) Controlling elements in Tn A, Tn 5and Tn 10 transposition d) Transposons in maize and Drosophila e) Retroviruses and retrotransposon, Ty elements in yeasts SINES, LINES and Alu elements	15

IV	**4. Proteomics** a) Basic concept of proteomics Expression, analysis and characterization of Protein. b) Analysis of protein structure c) Protein interaction. d) Basic concept of Metabolomics with examples and global biochemical networks	15

Suggested References MBCT 232 Molecular Biology : Semester III	
Unit I	**Genomics** 1. Alwi Z. B. (2005). The Use of SNPs in Pharmacogenomics Studies. *Malays J Med Sci.* 12(2):4-12. 2. Brown TA. (2002). Genomes. 2nd edition. Oxford: Wiley-Liss; Chapter 7, Understanding a Genome Sequence. Available from: https://www.ncbi.nlm.nih.gov/books/NBK21136/ 3. Butler J. M. (2012). Single Nucleotide Polymorphisms and Applications In: Advanced Topics in Forensic DNA Typing: Methodology. Academic Press: United States.347-369 4. Isenbarger T.A., Carr C.E., Johnson S.S., et al. (2008). The most conserved genome segments for life detection on Earth and other planets. Orig Life Evol Biosph. 38(6): 517-533. 5. Kaeberlein M. (2013). Longevity and aging. F1000Prime Rep. 5: 5. 6. Lemaître J. F., Berger V., Bonenfant C., Douhard M., Gamelon M., Plard F. and Gaillard J.M. (2015). Early-late life trade-offs and the evolution of ageing in the wild. *Proc Biol Sci.* 7; 282(1806): 20150209. 7. Morris B. J., Willcox B. J and Donlon T.A. (2019). Genetic and epigenetic regulation of human aging and longevity. Biochim Biophys Acta Mol Basis Dis. 1; 1865(7): 1718-1744. 8. Primrose S. B. and Twyman R. M. (2006). Principles of Gene Manipulation and Genomics, 7th Edition. S. B. Primrose & R. M. Twyman. Blackwell Publishing: U.S. 626 pp. 9. Ramírez-Bello J. and Jiménez-Morales M. (2017). Functional implications of single nucleotide polymorphisms (SNPs) in protein-coding and non- coding RNA genes in multifactorial diseases. Gac Med Mex. 153(2): 238- 250. 10. Shaw V., Bullock K. And Greenhalf W. (2016). Single-Nucleotide Polymorphism to Associate Cancer Risk. Methods Mol Biol. 1381: 93-110. 11. Stojanovic N., Florea L., Riemer C., Gumucio D., Slightom J., Goodman M., Miller W., and Hardison R. (1999). Comparison of five methods for finding conserved sequences in multiple alignments of gene regulatory regions, Nucleic Acids Research, 27 (19)1: 3899–3910. 12. Watson J. D., Baker T. A., Gann A., Bell S. P., Levine M. and Losick R. (2014). Molecular Biology of the Gene. 7th Edition. Pearson-USA 13. Yashin A. I., Ukraintseva S. V., Akushevich I. V., Arbeev K. G., Kulminski A. and Akushevich L. (2009). Trade-off between cancer and aging: what role do other diseases play? Evidence from experimental and human population studies. Mech Ageing Dev. 130(1-2): 98-104

<table>
<tr><td>Unit II</td><td>Genetically modified plants andanimals
1. Agnès E. Ricroch, Michèle Guillaume-Hofnung and Marcel Kuntz (2018). The ethical concerns about transgenic crops. Biochem J 475 (4): 803–811.
2. Cotrim A.P. and Baum B. J. (2008). Gene therapy: some history, applications, problems, and prospects. Toxicol Pathol. 36(1): 97-103.
3. Gene Therapy Tools and Potential Applications- Francisco Martin Molina (2013). Janeza Trdine 9, 51000 Rijeka, Croatia (online book)
4. Glick B. R. and Pasternak J. J. (1998). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington D C, ASM Press. http://library.um.edu.mo/ebooks/b28045804.pdf
5. Maghari B. M. and Ardekani A.M. (2011). Genetically modified foods and social concerns. Avicenna J Med Biotechnol. 3(3): 109-17.
6. Ormandy E.H., Dale J. and Griffin G. (2011). Genetic engineering of animals: ethical issues, including welfare concerns. Can Vet J. 52(5): 544- 550.
7. Weaver R. (2007). Molecular Biology. 4th Edition. Mc-Grew Hill Publication
8. Worgall S. and R. G. (2014). Gene Therapy In: Principles of Tissue Engineering (Fourth Edition). Academic Press: United States. Chapter 34. 657-686.</td></tr>
<tr><td>Unit III</td><td>Mobile DNA elements
1. Carnell A. M. and Goodman J.I. (2003). The Long (LINEs) and the Short (SINEs)of It: Altered Methylation as a Precursor to Toxicity. Toxicological Sciences. 75(2): 229–235
2. Griffiths A. J. F., Gelbart W. M., Miller J. H., et al. (1999). Modern Genetic Analysis. New York: W. H. Freeman; Ty Elements in Yeast. Available from:https://www.ncbi.nlm.nih.gov/books/NBK21285/
3. Kaminker J.S., Bergman C.M., Kronmiller B. et al. (2002). The transposable elements of the Drosophila melanogaster euchromatin: a genomics perspective. Genome Biol 3, research0084.1 (2002).
4. Konkel M. K., Walker J. A. and Batzer M. A. (2010). LINEs and SINEs of primate evolution.Evol Anthropol. 1; 19(6): 236-249.
5. Kramerov D. A. and Vassetzky N. S. (2011). Origin and evolution of SINEs in eukaryoticgenomes. Heredity (Edinb). 107(6): 487-95.
6. Krastanova O, Hadzhitodorov M. and Pesheva M. (2005). Ty Elements of theYeast Saccharomyces cerevisiae, Biotechnology & Biotechnological Equipment, 19(2): 19-26
7. Lewin B. (2011). Genes X. Jones and Bartlett Publication.
8. Lodish H. F. (2003). Molecular Cell Biology 5th Edition. New York: W Hand Freeman Company.
9. Reddy, A.R., Peterson, P.A. Transposable elements of maize. Molec Gen Genet 192: 21–31
10. Watson J. D., Baker T. A., Gann A., Bell S. P., Levine M. and Losick R. (2014). Molecular Biology of the Gene. 7th Edition. Pearson-USA
11. Weiner A. M. (2002). SINEs and LINEs: The art of biting the hand thatfeeds you. Current Opinion in Cell Biology. 14(3): 343-350</td></tr>
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Unit IV	**Proteomics** 1. Baidoo E. E. K. (2019). Microbial Metabolomics: A General Overview.Methods Mol Biol.1859: 1-8. 2. Banaei-Esfahani A, Nicod C, Aebersold R, Collins BC. (2017). Systems proteomics approaches to study bacterial pathogens: application to Mycobacterium tuberculosis. Curr Opin Microbiol. 39:64-72. 3. Chen B, Zhang D, Wang X, Ma W, Deng S, Zhang P, Zhu H, Xu N, Liang S. (2017). Proteomics progresses in microbial physiology and clinical antimicrobial therapy. Eur J Clin Microbiol Infect Dis. 36(3): 403- 4. Chen F, Ma R, Chen XL. (2019). Advances of Metabolomics in Fungal Pathogen-Plant Interactions. Metabolites. 15; 9(8): 169. 5. Ekman R., Silberring J., Brinkmalm A. W. and Kraj A. (2009). Mass Spectrometry: Instrumentation, interpretation and applications, John Wiley and Sons. Inc., Canada. 6. Graves P.R. and Haystead T. A. (2002). Molecular biologist's guide to proteomics. Microbiol Mol Biol Rev. 66(1):3 9-63. 7. Kellner R. (2000). Proteomics: Concepts and perspectives. Fresenius J Anal Chem. 366(6-7): 517-524. 8. Figeys D. (Editor). (2005). Industrial Proteomics: Applications for Biotechnologyand Pharmaceuticals. Preface. Methods Biochem Anal. 45: vii-viii. PMID: 19235289. https://analyticalscience.wiley.com/do/10.1002/sepspec.10201education/full/ 9. Luger K. and Phillips S.E. (2010). Protein-Nucleic acid interactions. Curr Opin Struct Biol. 20(1): 70-72. 10. Nölting B. (2006). Methods in Modern Biophysics. Second Edition, Springer: Germany. 11. Patwaradhan B. and Chaguture R. (2005). An overview of the basics of proteomics.In: Innovative approaches in drug discovery, Academic Press: United States. 12. Ramanathan M., Porter D.F. and Khavari P.A. (2019). Methods to study RNA-protein interactions. Nat Methods. 16(3): 225-234. 13. Tang J. (2011). Microbial metabolomics. Curr Genomics. 12(6): 391-403. 14. Villas-Bôas S. (2012). Katya Ruggiero Microbial Metabolomics CABI. 15. Webster D. (2000). Protein Structure, Prediction methods and Protocols. Methods in Molecular Biology Vol 143 Humana Press. 16. Wilson K. And Walker J. (2005). Principles and Techniques of Biochemistry and Molecular Biology, 6th Edn., Cambridge University Press, New York. 17. Zhao J., Wang G., Chu J. and Zhuang Y. (2019). Harnessing microbial metabolomics for industrial applications. World J Microbiol Biotechnol. 36(1): 1-8.

Semester III

23-MBCT-233: Clinical Microbiology

Core Compulsory Theory Paper

[4 Credits; 60 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:

Students will be able to:

CO1: Describe determinants of pathogenicity, modes of action of different bacterial toxins

CO2: Explain significance of epidemiological modelling, use of mathematical models, modified epidemiological model for COVID 19 pandemic

CO3: Describe different bacterial, fungal and parasitic infections and their respective epidemiology, pathogenicity, diagnosis, prevention

CO4: Explain different viral diseases, significance of their study in current situation, epidemiology, pathogenicity mechanism, their laboratory diagnosis, therapeutic agents, prevention

Unit	Title and Content	Lectures
I	**A. Determinants of Microbial Pathogenicity** i. Adhesion ii. Invasion iii. Evasion iv. Toxigenesis (mode of action –In vivo and In vitro assay systems for diphtheria, cholera, tetanus toxoid and endotoxins of Gram negative bacteria) v. Bacterial resistance to host defenses- Phagocytosis, specific and nonspecific humoral factors) vi. Molecular basis of bacterial pathogenicity – Cytoskeletal modulation of host cell. Virulence genes and pathogenicity islands.	**15**
	B. Disease Prediction Epidemiological Models: i. Introduction to epidemiological modeling for infectious diseasedynamics ii. Types of Models: a. Susceptible infectious recovered (SIR) b. Susceptible exposed infectious recovered(SEIR) iii A case study: Disease Prediction Epidemiological ModelsCOVID 19	

II	Bacterial diseases with respect to causative agents, general characters, detection methods, therapeutic agents and prophylaxis. Handling and disposing of infectious material i. *Helicobacter pylori* ii. *Campylobacter jejuni* iii. *Mycobactertium tuberculosis* iv. *Acinetobacter boumanii* v. *Actinomycetes bovis/israelli*	**15**
III	Viral diseases with respect to causative agents, general characters, detection method, therapeutic agents and prophylaxis. Handling and disposing of infectious material. i. Hepatitis B ii. H1N1 iii. HIV iv. Oncoviruses v. Ebola Virus	**15**
IV	Fungal & protozoal diseases with respect to causative agents, generalcharacters, detection methods, therapeutic agents and prophylaxis. Handling and disposing of infectious material i. *Candida albicans* ii. *Trichophyton metagrophytes* iii. *Aspergillus flavus* iv. *Entamoeba histolytica* v. *Ascaris lumbricoides* vi. *Giardia lamblia*	**15**

Suggested References 23-MBCT-233Clinical Microbiology Semester III	
Unit	**References**
I	**A. Determinants of Microbial Pathogenicity** 1. Gal-Mor B. and Finlay B. B. (2006). Pathogenicity islands: a molecular toolbox for bacterial virulence. Cellular Microbiology. 8 (11): 1707-1719. 2. Iglewski B. H. (1990). Molecular Basis of Bacterial Pathogenesis, first edition, Academic Press: United States. 3. Kudva I. T., Cornick N. A., Plummer P. J., Zhang Q., T. L., Bannantine J.P. and Bellaire B. H. (2016). Virulence Mechanisms of Bacterial Pathogens. Fifth Edition, ASM: Washington. 4. Peterson J. W. (1996). Bacterial Pathogenesis In: Medical Microbiology. 4th Edition. Editor by Samuel Baron, Galveston, Texas, Link to the book: https://www.ncbi.nlm.nih.gov/books/NBK8526/ 5. Rosenberg E. (2005). The diversity of bacterial pathogenicity mechanisms. GenomeBiol. doi: 10.1186/gb-2005-6-5-320 6. Schmidt H. and Hensel M. (2004) Pathogenicity islands in bacterial pathogenesis. ClinMicrobiol Rev. 17(1): 14-56. **B. Disease Prediction Epidemiological Models:** 1. Hethcote H. W. (1989). The basic epidemiology models: models, expressions for r0, parameter estimation, and applications mathematical understanding of infectious disease dynamics. © World Scientific Publishing Co. Pte. Ltd. 1-61 2. Li L., Yang Z., Dang Z., Meng C., Huang J., Meng H., Wang D., Chen G., Zhang J., Peng H. and Shao Y. (2020). Propagation analysis and prediction of the COVID-19. Infect Dis Model, 5: 282-292 3. Siettos C.I. and Russo L. (2013). Mathematical modeling of infectious disease dynamics. Virulence. 4(4): 295-306. 4. Wearing H. J., Rohani P. and Keeling M. J. (2005). Appropriate models for the management of infectious diseases. PLoS Med 2(7): e174 5. Yang Z., Zeng Z., Wang K., Wong S., *et al*., (2020). Modified SEIR and AI prediction of the epidemics trend of COVID-19 in China under public health interventions. Journal of Thoracic Disease. 12(3): 165-174

II	1. Asif M., Alvi I.A. and Rehman S.U. (2018). Insight into Acinetobacter *baumannii*: pathogenesis, global resistance, mechanisms of resistance, treatment options, and alternative modalities. Infect Drug Resist. 11:.1249- 1260. https://www.intechopen.com/books/mycobacterium-research-and-development/virulence-factors-and-pathogenicity-of-mycobacterium. 2. Delogu G., Sali M. and Fadda G. (2013). The biology of *Mycobacterium tuberculosis* infection. Mediterr J Hematol Infect Dis. 16; 5(1): e2013070. 3. Echeverria-Valencia G., Flores-Villalva S.and Espitia C.I. (2017). Virulence Factors and Pathogenicity of *Mycobacterium*. Chapter 12. Mycobacterium - Research and Development. Editor-Wellman Ribón, IntechOpen. 4. Idowu A., Mzukwa, A., Harrison, U., Palamides P., Haas R., Mbao M., Mamdoo R., Bolon J., Jolaiya T., Smith S., Ally R., Clarke A. and Njom H. (2019). Detection of *Helicobacter pylori* and its virulence genes (*cag*A, *dup*A and *vac*A) among patients with gastroduodenal diseases in Chris Hani Baragwanath Academic Hospital, South Africa. *BMC Gastroenterol*.19:.73. 5. Jianjun S., Champion P. A. and Bigi F. (2019). Cellular and Molecular Mechanisms of *Mycobacterium tuberculosis* Virulence. Frontiers in Cellular and Infection Microbiology.9:.331. 6. Joly-Guillou ML. (2005). Clinical impact and pathogenicity of Acinetobacter. Clin Microbiol Infect. 11(11):.868-873. 7. Kao C. Y., Sheu B. S. and Wu J. J. (2006). *Helicobacter pylori* infection: An overview ofbacterial virulence factors and pathogenesis. Biomedical Journal. 39(1): 14-23 8. Kusters J. G., van Vliet A. H. and Kuipers E. J. (2006). Pathogenesis of *Helicobacter pylori* infection. Clin Microbiol Rev. 19(3):.449-490. 9. Lee C. R., Lee J. H, Park M., Park K. S., Bae I. K., Kim Y. B., Cha C. J., Jeong B. C.and Lee S. H. (2017). Biology of *Acinetobacter baumannii*: Pathogenesis, Antibiotic Resistance Mechanisms, and Prospective Treatment Options. Front Cell Infect Microbiol. 13: 7:55. 10. Levin R. E. (2007). *Campylobacter jejuni*: A review of its characteristics, pathogenicity, ecology, distribution, subspecies characterization and molecular methods of detection. Food biotechnology. 21(4): .271-347. 11. Misawa N. and Blaser M. J. (2000) Detection and characterization of autoagglutination activity by *Campylobacter jejuni*. Infection and Immunity. 68(11): 6168-6175. 12. Morris F. C., Dexter C., Kostoulias X., Uddin M. I. and Peleg A. Y. (2019). The mechanisms of disease caused by *Acinetobacter baumannii*. Front. Microbiol. 10: 1601. 13. Nyati K. K. (2013). Role of *Campylobacter jejuni* Infection in the Pathogenesis of Guillain-Barré Syndrome: An Update. Biomedical Research Journal. 1-13. 14. Pine L., Howell A. Jr and Watson S. J. (1960. Studies of the morphological, physiological, and biochemical characters of *Actinomyces bovis*. J Gen Microbiol. 23: 403-424. 15. Ricke S. C., Feye K. M., Chaney W. E., Shi Z., Pavlidis H. and Yang Y. (2019). Developments in rapid detection methods for the detection of foodborne *Campylobacter* in the United States. Front Microbiol. 9: 3280. 16. Sharma S., Hashmi M. F. and Valentino III D. J. (2020). Actinomycosis. In:

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III	1. Chauhan N., Narang J., Pundir S., Singh S. and Pundir C. S. (2012). Laboratory diagnosis of swine flu: A review. Artificial cells, blood substitutes and immobilization biotechnology. 41(3): 189-195 2. Chisari F.V., Isogawa M. and Wieland S.F. (2010). Pathogenesis of Hepatitis B virus infection. Pathol Biol (Paris). 58(4): 258-66. 3. Falasca L., Agrati C., Petrosillo N., Di Caro A., Capobianchi M. R., Ippolito G. and Piacentini M. (2015). Molecular mechanisms of Ebola virus pathogenesis: focus on celldeath. Cell Death Differ. 22(8): 1250-1259. 4. Jilani T. N., Jamil R. T. and Siddiqui A. H. (2020). H1N1 Influenza (Swine Flu) In: StatPearls [Internet]. Treasure Island (FL): StatPearls. Available from: https://www.ncbi.nlm.nih.gov/books/NBK513241/ 5. Kawai Y., Kimura Y., Lezhava A, *et al*. (2012). One-step detection of the 2009 pandemic influenza A (H1N1) virus by the RT-Smart Amp assay and its clinical validation. *PLoS One*. 7(1): e30236. 6. Khalafallah M. T., Aboshady O. A., Moawed S. A. and Ramadan M. S. (2017). Ebola virus disease: Essential clinical knowledge. Avicenna J Med. 7(3): 96-102. 7. Krajden M., McNabb G. and Petric M. (2005). The laboratory diagnosis of Hepatitis B virus. Can J Infect Dis Med Microbiol.16 (2): 65-72 8. Ravina R., Dalal A, Mohan H., Prasad M. and Pundir C.S. (2020). Detection methods for influenza A H1N1 virus with special reference to biosensors: a review. Biosci Rep. 40(2): BSR20193852 9. Rewar S., Mirdha D. and Rewar P. (2015). Treatment and prevention of pandemic H1N1 influenza. *Ann Glob Health*. 81(5): 645-653. doi: 10.1016/j.aogh.2015.08.014. 10. Simon V., Ho D.D. and Abdool Karim Q. (2006). HIV/AIDS epidemiology, pathogenesis, prevention, and treatment. Lancet. 5; 368(9534):.489-504. 11. Sullivan N., Yang Z.Y. and Nabel G. J. (2003). Ebola virus pathogenesis: implications for vaccines and therapies. J Virol. 77(18): 9733-9737. 12. Wilkins T., Sams R. and Carpenter M. (2019). Hepatitis B: Screening, prevention, diagnosis, and treatment. Am Fam Physician. 99(5): 314-323. 13. Wu C.C., Chen Y.S., Cao L., Chen X.W. and Lu M.J. (2018). Hepatitis B virus infection: Defective surface antigen expression and pathogenesis. World J Gastroenterol. 21; 24(31): 3488-3499.

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Semester III

23-MBCP-234: Practical based on Compulsory theory credits
Total Workload: - 4 credits = 120 hrs in semester

Course Outcomes:

Students will be able to:

CO1: Apply various immunological techniques such as immuno-electrophoresis, SRID, agglutination for detection of virus.

CO2: Carry out Plasmid Isolation, Separation using electrophoretic method and design an experiment to study bacterial transformation & conjugation.

CO3: Identify fungal and bacterial pathogens by cultural and biochemical characteristics

Units	Title and Contents	Lectures
I	**Practicals based on MBCT 231: Immunology** 1. Viral titre determination by haemagglutination 2. Rocket Immuno – electrophoresis 3. Preparation of serum from the blood sample and analysis of its proteins by electrophoresis a. Preparation of serum from whole blood sample. b. Separation of serum proteins by agarose gel electrophoresis. c. Analysis of separated protein fractions by densitometry(by Image J software). 4. Demonstration of PCR 5. Visit to Institute/ Industry for demonstration of ELISPOT/ CFT/FACS/animal inoculation	40
II	**Practicals based on MBCT 232 Molecular Biology** 1. Isolation of Plasmid from Bacteria by Alkaline lysis method 2. Preparation of competent cells by $CaCl_2$ method 3. To Perform Transformation by using suitable Plasmid 4. To check the efficiency of transformation using Blue white screening method 5. Demonstration of gene transfer by bacterial conjugation	40

III	**Practicals based on MBCT 233: Clinical Microbiology** **A.** Isolation, identification and antibiotic sensitivity testing of (any three) *1. Actinomycetes* *2. Acinetobacter* *3. Clostridium* *4. Corynebacterium* *5. Vibrio*	21
	B. Isolation, identification and antibiotic sensitivity testing of (any two) *1. Candida albicans* *2. Trichophyton mentagrophytes* *3.Aspergillus flavus*	14
	C. Demonstration of cultivation of viruses by egg inoculation technique with pock and plaque detection	05

Suggested References 23-MBCP-234: Immunology, Molecular Biology and Clinical microbiology

Unit	References
I	1. Axelsen N. H., Kroll J. and Weeke B. (1973). A manual of quantitative immunoelectrophoresis: methods and applications. Scand. J. Immunol. 2(Suppl. 1): 37- 46 2. Galvão de França N.D., Cristovão Poli M.C., Almeida Ramos P.G., Rocha Borsoi C.S. and Colella R. (2011). Titers of ABO antibodies in group O blood donors.Rev Bras Hematol Hemoter. 33: 259–262 3. Laurell C. B. (1966). Quantitative estimation of proteins by electrophoresis in agarose gel containing antibodies. Anal. Biochem. 15: 45–52 4. Alexander D.J. and Chettle N.J. (1977) Procedures for the haemagglutination and the haemagglutination inhibition tests for avian infectious bronchitis virus. Avian Pathology. 6(1):9-17 2. 5. Costabile M. (2010) Determining the Reactivity and Titre of Serum using a haemagglutination Assay J Vis Exp. 2010; (35): 1752. Published online 6. Noah D.L., Hill H., Hines D., White E.L.and Wolff M.C. 2009 Qualification of the hemagglutination inhibition assay in support of pandemic influenza vaccine licensure. Clinical and Vaccine Immunology: CVI. 16(4):558-566. 7. World Health Organization. WHO Collaborating Center for Reference and Research on Influenza Chinese National Influenza Center National Institute for Viral Disease Control and Prevention, China CDC (2013) Laboratory Procedures. (20 December 2013) Serological detection of avian influenza A(H7N9) virus infections by modified horse red blood cells haemagglutination-inhibition assay 8. Garibyan, L., & Avashia, N. (2013). Polymerase chain reaction. *The Journal of investigative dermatology*, *133*(3), 1–4. https://doi.org/10.1038/jid.2013.1 9. Coleman, W.B., Tsongalis, G.J. (2006). The olymerase Chain Reaction. In: Coleman, W.B., Tsongalis, G.J. (eds) Molecular Diagnostics. Humana Press. https://doi.org/10.1385/1-59259-928-1:047

II	1. Green M. R. and Sambrook J. (2018). The Hanahan Method for Preparation and Transformation of Competent *Escherichia coli*: High-Efficiency Transformation. ColdSpring Harb Protoc. (3): 10. 2. Griffiths A. J. F., Miller J. H., Suzuki D. T., et al. (2000). An Introduction to Genetic Analysis. 7th edition. New York: W. H. Freeman; Bacterial conjugation. https://www.ncbi.nlm.nih.gov/books/NBK21942/ 3. Phornphisutthimas S., Thamchaipenet A. and Panijpan B. (2007). Conjugation in *Escherichia coli*: A laboratory exercise. Biochem Mol Biol Educ. 35(6): 440-445. 4. Sambrook J. and Russell D. (2001). Molecular Cloning: A Laboratory Manual, 3rd edition. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press. 5. Wilson K. and Walker J. (2005). Principles and Techniques of Biochemistry and Molecular Biology. 6th Edition., Cambridge University Press, New York
III	**A.** Isolation and identification of 1. Meera Kumari, Bat-Erdene Myagmarjav, Birendra Prasad and Madhusudan Choudhary (2013). Identification and characterization of antibiotic-producing actinomycetes isolates. American Journal of Microbiology 4 (1): 24-31, 2013 ISSN: 1948-982x © 2013 Science Publications doi:10.3844/ajmsp.2013.24.31 2. Anupama Sapkota,Aishwarya Thapa, Anupa Budhathoki, Muskan Sainju,Prativa Shrestha and Sagar Aryal (March 2020). Isolation, Characterization, and Screening of Antimicrobial-Producing Actinomycetes from Soil Samples. International Journal of Microbiology Volume 2020 |Article ID 2716584 | https://doi.org/10.1155/2020/2716584. 3. Neetu Gupta, Nageswari Gandham, Savita Jadhav and Ravindra Nath Mishra (2015). Isolation and identification of Acinetobacter species with special reference to antibiotic resistance. J Nat Sci Biol Med. 2015 Jan-Jun; 6(1): 159–162. doi: 10.4103/0976-9668.149116 4. Shojadoost, B.; Peighambari, S.M. and Nikpiran, H. (2010). Isolation, identification and antimicrobial susceptibility of *Clostridium perfringens* isolates from acute necrotic enteritis of broiler chickens. Int.J.Vet.Res. (2010), 4; 3: 147-151 5. BS Reddy, A Chaudhury, U Kalawat, R Jayaprada, GSK Reddy, BV Ramana (2012). Isolation, speciation and antibiogram of clinically relevant non-diphtherial
	B. Isolation and identification of (any two fungal pathogens) 1. Baxter M. (1966) Isolation of *Trichophyton mentagrophytes* from British soil. Sabouraudia. 4: 207–209. 2. Joshi K. R. and Gavin J. B. (1974). A simple laboratory method for the rapid identification of *Candida albicans*. Pathology. 6(3): 231-233. 3. Meinhof W., Laschka P. and Scherwitz C. (1975). A synthetic medium for rapid chlamydospore formation in *Candida albicans*. Mykosen. 18(7): 291-298. 4. Gunasekaran M. and Hughes W. F. (1977). A simple medium for isolation and identification of *Candida albicans* directly from clinical specimens. *Mycopathologia*.61(3): 151-157. 5. Baxter M. (1966). Isolation of *Trichophyton mentagrophytes* from British soil, *Sabouraudia*, 4: 207–209. 6. Sinski J. T., Kelley L. M., Flynt P. M. and Miegel J. (1977). Dermatophyte isolation media: quantitative appraisal using skin scales infected with *Trichophyton mentagrophytes* and *Trichophyton rubrum*. J Clin Microbiol. 5(1): 34-38. Taber R. A. and Schroeder H. W. (1967). Aflatoxin-producing potential of isolates of the *Aspergillus flavus*- oryzae group from peanuts (*Arachis hypogaea*). Appl Microbiol. 15(1):140-144.

Semester III

23-MBET-235: Cell Culture techniques

Choice based Optional Theory Paper (Elective)

[2 Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course outcomes:

CO1: Students will be able to describe various methods of Cell Culture Techniques

CO2: Student will gain knowledge of Immuno-modulation caused by agents activating or suppressing immune system function.

Unit	Title and Contents	Lectures
I	**Animal Cell Culture Techniques:** A. Definition of terms: Primary cell cultures and cell lines, establishedcell lines, suspension and anchorage dependent cell cultures. B. Transformation of cells in culture, culture media, factors affectingcells in culture.	15
II	**Commonly used cell culture systems and cell lines in immunologicalstudies:** A. Cell culture systems and their applications: primary lymphoid cellculture cloned lymphoid cell lines, hybrid lymphoid cell lines. B. Immuno-modulation	15

Suggested References 23-MBET: 235 Cell Culture Techniques	
Unit	**References**
I	**Animal Cell Culture Techniques:** 1. Freshney R. I. (2005). Culture of Animal Cells: A Manual of Basic Technique.5th Ed. John Wiley and Sons, Inc. 2. Masters J. R. W. (2000). Animal Cell Culture – A Practical Approach. 3rdEd. Oxford University Press. 3. Mather J. P. and Penelope E. R. (1998). Introduction to Cell and TissueCulture Theory and Technique. Plenum Press, New York
II	**Commonly used cell culture systems and cell lines in immunological studies:** 1. Kindt T. J., Goldsby R. A., Osborne B. A. and Kuby J. (2007). Kuby Immunology. 6th Ed. W. H. Freeman and Co. 2. Patwardhan B., Diwanay S.and Gautam M. (2006). Botanical immunomodulators and chemoprotectants in cancer therapy. In Drug Discovery and Development Volume I: Drug Discovery. Ed. Chorghade Mukund S. Wiley Interscience, John Wiley and Sons Inc. USA. 405-424.

Semester III

23-MBEP-235: Practicals Based on Cell Culture techniques

Choice based Optional Practical Paper (Elective)
(Total Workload): - 2 credits x 30 hrs = 60 hrs in semester

Course Outcomes:

Students will be able to

CO1: Culture lymphocytes and Study effect of immunomodulators

CO2: Culture chick embryo fibroblast cells.

Unit	Title and Contents	Lectures
I	**Practicals based on Animal Cell Culture Techniques:** A. Density gradient based separation of peripheral lymphocytes B. Preparation of Lymphocyte culture C. Effect of immunomodulators on lymphocyte proliferation (Stimulatory and inhibitory effect)	30
II	**Practicals based on Commonly used cell culture systems and celllines in immunological studies:** A. Chick embryo fibroblast cell culture	30

Suggested References 23-MBEP: 235 Practicals based on Cell Culture Techniques:Semester III Choice based Optional Practical Paper (Elective)	
Unit	**References**
I	**Practicals based on Animal Cell Culture Techniques:** 1. Freshney R. I. (2005). Culture of Animal Cells: A Manual of Basic Technique, 5th Ed., John Wiley and Sons, Inc 2. Masters J. R. W. (2000). Animal Cell Culture – A Practical Approach. 3rdEd. Oxford University Press.
II	**Practicals based on Commonly used cell culture systems and cell lines inimmunological studies:** 1. Mather J. P. and Penelope E. R. (1998). Introduction to Cell and TissueCulture Theory and Technique. Plenum Press, New York 2. Hernandez R. and Brown D.T. (2010). Growth and maintenance of chickembryo fibroblasts (CEF). Curr Protoc Microbiol.17: A.4I.1–A.4I.8

Semester III

23-MBEP-236: Experimental Design and Quantitative approach for Biologist

Choice based Optional Theory Paper (Elective)

[2 Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:

The students will be able to

CO1: Understand design of experiments and survey design

CO2: Explain methodology of clinical trials and epidemiological studies

CO3: Present experimental data in various forms of data representation.

CO4: Explain various mathematical models

Unit	Title and Contents	Lectures
I	**Designing of Experiments** 1. Research Methodology 2. Sampling methods, sampling errors 3. Survey design, Design of Experiments in Agriculture (randomization, replication and local control), Experimental designs-CRD, RCBD and LSD 4. Factorial design (Full, Fractional and Plackett Burman) 5. Epidemiological Study designs: Case control, cohort, concurrent, cross-sectional, retrospective/prospective 6. Clinical/field trials-Randomization, Bias removal (Blinding – single &double), controlled and uncontrolled trials	(15)
II	**Mathematical approach for Biologists** *(Basic rules and application of limits, derivative and integration need to be discussed)* 1. Presentation of experimental data (Tables, graphs and equations) 2. Data Analysis (Trends, Testing mathematical models, Goodness of fit:Least Square Analysis, Linear and Non-linear models) 3. Concept of mathematical model, need, modelling the system of interest, modelling the data Deterministic Vs Stochastic model, Cyclic processes ofmodel construction, verification and applications	(15)

Semester III

23-MBEP-236: Practicals based on Experimental Design and Quantitative approach for Biologist

Choice based Optional Practical Paper (Elective)

(Total Workload): - 60 hrs in semester

Course outcomes

CO1: Students will be capable of writing a research proposal
CO2: Students will be able to carry epidemiological and statistical surveys
CO3: Students will be able to perform numerical calculations in microbiology related topics, to use software relevant to data analysis and data representation using several mathematical models.

Unit	Title and Contents	Lectures
I	1. Designing of Mock Research Proposal which includes: a) Title b) Hypothesis c) Review of Literature d) Methodology (Specify Statistical Methods) e) Possible outcomes (Statistical Interpretations) f) References Scientific writing should be followed for Research proposal	**20**
II	Epidemiological/statistical survey (Mini Project) a) Identification of Problem and Establishing Hypothesis b) Selection of Design c) Data Collection d) Data Analysis e) Data Presentation f) Conclusion (Data can be collected from Research papers/ Dissertations/ Journals)	**20**
III	Factorial Study Design (Plackett- Burmen, Fractional Factorial and full factorial) for Optimization of Media conditions (Data collection from Research Papers/ Dissertations /Journals)	**10**
IV	Numerical Microbiology Problem solving: Unit conversion, Numerical Problems on size, volume, number (CFU and PFU), dilutions, Neubauer chamber, direct microscopic count, Numerical Problems on Bacterial Growth. Numerical problems on diversity indices	**10**

Suggested References 23-MBEP-236: Practicals based on Experimental Design and Quantitative approach for Biologist: Semester III	
Unit	**References**
I	**1. Designing of Mock Research Proposal which includes:** a. Gastel B. and Day R. A. (2016). How to Write and Publish a Scientific Paper. United States: ABC-CLIO, LLC. Kothari C. R. (2004). Research methodology methods and techniques. 2 nd revised edition. New age international publisher. 2. Epidemiological study Proposal (Mini Project) b. Brown D. and Rothery P. (1993). Models in biology: mathematics, statistics, and computing. United Kingdom: Wiley. ISBN: 9780471933229. Digitized 20th June 2009 Newman S. C. (2003). Biostatistical Methods in Epidemiology. Germany: Wiley ISBN: 9780471461609 3. Statistical Survey c. Acharya R. and Roy T. K. (2016). Statistical Survey Design and Evaluating Impact.India: Cambridge University Press. d. Nardi P. M. (2018). Doing Survey Research: A Guide to Quantitative Methods. United Kingdom: Taylor & Francis. e. Singh Y. K. (2006). Fundamental of Research Methodology and Statistics. India: New Age International (P) Limited. 4. Factorial Study Design (Placket barmen, Fractional Factorial and full factorial) for Optimization of Media conditions f. Harvey L. and McNeil B. (2008). Practical Fermentation Technology. Germany: Wiley. g. Montgomery D. C. (2013). Design and Analysis of Experiments. Italy: Wiley.
II	**Credit II: Practicals based on Theory Mathematical approach for Biologists** 1. **Numerical Microbiology Problem solving: Unit conversion, Numerical Problems on size, volume, number (CFU and PFU), dilutions, Neubauer chamber, direct microscopic count, Numerical Problems on Bacterial Growth. Numerical problems on diversity indices** a. Aneja K. R. (2007). Experiments in Microbiology, Plant Pathology and Biotechnology. India: New Age International. b. Cappuccino J. G. and Welsh C. T. (2017). Microbiology: A Laboratory Manual. eBook, Global Edition. United Kingdom: Pearson Education. c. Green L. H. and Goldman E. (2008). Practical Handbook of Microbiology. United States: CRC Press. d. Pommerville J. C. (2010). Alcamo's Laboratory Fundamentals of Microbiology. United States: Jones & Bartlett Learning, LLC. e. Tate R. L. (1986). Microbial Autecology: A Method for Environmental Studies. Digitized 2009. United Kingdom: Wiley. 2. Computer applications: Using data sheets, and sorting data with different parameters, plotting graphs – bar charts, line graphs, pie charts, adding error bars. (Using Statistical Packages other than Microsoft Excel) f. Boslaugh S. (2012). Statistics in a Nutshell. Germany: O'Reilly Media Incorporated. g. Conner N. and MacDonald M. (2013). Office 2013: The Missing Manual. United States: O'ReillyMedia. h. McFedries P. (2019). Microsoft Excel 2019 Formulas and Functions. Pearson Education. i. Khan I. A. and Khanum A. (2016). Fundamentals of Biostatistics. 5th Edition. Ukaaz, Publications, Hyderabad. ISBN-13: 9788190044103 j. McFedries P. (2019). Microsoft Excel 2019 Formulas and Functions. Pearson Education k. Salkind N. J. (2016). Statistics for People Who (Think They) Hate Statistics: Using Microsoft Excel2016. United States: SAGE Publications

Semester III

23-MBET-237: Microbial Virus Technology

Choice based Optional Theory Paper (Elective)

[2 Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course outcomes:
CO1: Students will understand the basics of isolation and characterization of bacteriophages.
CO2: They will be able to know various concepts of bacteriophage growth kinetics
CO3: Pupil shall also learn about Phage typing.

Unit	Title and Contents	Lectures
I	**A. Isolation and characterization of bacteriophages** i. Abundance of bacteriophages in the environment ii. Bacteriophage Lifecycle-Lytic, Lysogeny and chroniccycle. Genetic basis of lytic and lysogeny cycles	05
	B. Isolation of bacteriophages from various environmental samples- (Different methods) i River, Intestine, Lakes, Tooth plaque, Ponds, High temperature environment Cockroaches, Raw vegetables, Activated sludge, Fecal matter, Sewage , Soil, Flies, Sewage Treatment plant	03
	C. Bacteriophage growth kinetics i. Concept and calculations of EoP, MOI ii. Adsorption rate constant iii. One step growth curve-(Latent period, Eclipsed period, Rise period, Plateau, burst size	05
	D. Phage based bacterial detection: Phage typing	02
II	**A. Bacteriophage as biocontrol agent** i. Phage based technology for decontamination of water (drinkingwater, recreational water, medical waste water) ii. Phage based technology for pathogen control in aqua systems iii. Bacteriophages for the biocontrol of biofilms on medical devices iv. Bacteriophage based technology for pathogen control in Poultry	05
	B. Bacteriophage Therapy i. Use of bacteriophages as therapeutic agent **ii.** Phage lysine therapy and prophylaxis	04

	C. Mycoviruses: A new dimension in Microbiology i. Occurrence ii. Taxonomy of Mycoviruses iii. Mycovirus-host interaction mechanisms iv. Characterization Techniques v. Mycoviruses as biocontrol agents against fungal plant pathogens	05
	D. Introduction of algal viruses	01

Suggested References 23-MBET-237: Microbial Virus Technology : Semester III

Unit	References
I	**A** 1. Ahiwale S. (2013). Bacteriophages against enteric bacterial pathogens and their potential for bioremediation of pathogen infested water bodies. PhD thesis, University of Pune, Pune, Maharashtra 2. Rohwer F., Youle M., Maughan H. and Hisakawa N. (2014). Life in Our Phage World. A centennial field guide to the Earth's most diverse inhabitants. Illustrations by Leah L Pantéa and Benjamin Darby (Book) 3. Hobbs Z. and Abedon S. T. (2016). Virology Diversity of phage infection types and associated terminology: the problem with Lytic or lysogenic. Mini review. FEMS Microbiology Letters, 363, , fnw047 doi: 10.1093/femsle/fnw047, 2016
	B 1. Ahiwale S. (2013). Bacteriophages against enteric bacterial pathogens and their potential for bioremediation of pathogen infested water bodies. PhD thesis, University of Pune, Pune, Maharashtra 2. Azeredo J. and Sillankorva S. Editors. (2018) Bacteriophage Therapy from Lab to Clinical Practice. In Methods in Molecular Biology. Walker J. M. Series Editor. Humana Press Book. Springer. 3. Clokie M. R. J. and Kropinski A. M. Editors (2009). Bacteriophages: Methods and Protocols. Volume1: Isolation, Characterization and Interactions. Springer Book
	C 1. Clokie M. R. J. and Kropinski A. M. Editors (2009). Bacteriophages: Methods and Protocols. Volume1: Isolation, Characterization and Interactions. Springer Book Effect of bacterial growth rate on bacteriophage population growth rate, Dominik Nabergoj, Petra Modic, Ales Podgornik,Wiley Microbiology open, 2017
	D 1. Schofield D.A., Sharp N.J. and Waste Water C. (2012). Phage-based platforms for the clinical detection of human bacterial pathogens. Bacteriophage. 2(2): 105-283

II	**A. i.** 1. Ahiwale S. (2013) Bacteriophages against enteric bacterial pathogens and their potential for bioremediation of pathogen infested water bodies. PhD thesis, University of Pune, Pune, Maharashtra 2. McLaughlin M. R. and Brooks J. P. (2008) EPA worst case water microcosms for testing phage biocontrol of *Salmonella*. J Environ Qual. 37: 266-271 3. Sharma S., Soumya Chatterjee S., Datta S., Rishika Prasad R., Dubey D., Prasad R. K. and Vairale M.G. (2017). Bacteriophages and its applications: an overview. Folia Microbiol. 62(1):17-55 4. Singh M.K., Maurya A. and Kumar S. (2020). Bio augmentation for the treatment of waterborne pathogen contamination water. Waterborne Pathogens. 189-203 **A. ii.** 1. Culot A., Grosset N. and Gautier M. (2019). Overcoming the challenges of phage therapy for industrial aquaculture: A review. Aquaculture. Elsevier. 513:734423. 2. Kutter E. and Sulakvelidze A. Editors. (2004). Bacteriophages: Biology and Applications. Edition-illustrated. Publisher-CRC Press. 3. Nakai T. and Park S. C. (2002). Bacteriophage therapy of infectious diseases in aquaculture. Mini-review. Research in Microbiology. 153: 13–18 4. Vinod M. G., Shiva M.M., Umesha K.R., Rajaveera B.C., Krohne G. and Karunasagar J. (2006). Isolation of *Vibrio harveyi* bacteriophage with potential for biocontrol of luminous vibriosis in hatchery environments. Aquaculture. 55: 117-124 **A. iii.** 1. Ahiwale S. S. (2011). *In vitro* management of hospital *Pseudomonas aeruginosa* biofilm using indigenous T7-like lytic phage. Curr. Microbiology. 62: 335-340 2. Haradaa L. K., Silvaa E.C., Camposa W. F., Del Fiola F. S., Vilaa M., Dąbrowskab K., Krylovc V. N. and Balcão V. M. (2018). Applications of bacteriophages: State of the art, Review article. Microbiol Res. 212- 213: 38-58 3. Lu T. K. and Collins J. J. (2007). Dispersing biofilms with engineered enzymatic bacteriophage. Proceedings of National Academy of Science. 104: 11197-11202 **A. iv.** 1. Gorski A., Miedzybrodzki R. and Borysowski J. (Editors). (2019). Phage Therapy: A Practical Approach.Springer International Publishing 2. Żbikowska K, Michalczuk M. and Dolka B. (2020). The Use of Bacteriophages in the Poultry Industry.Review. Animals (Basel).10(5): 872

	B. Bacteriophage Therapy 1. Eric E. C. and Adhya S. L. (2015). Phage Therapy: Current Research and Applications. Clinical infectious diseases: an official publication of the Infectious Diseases Society of America. 61(1): 141–142 2. Gorski A., Miedzybrodzki R. and Borysowski J. (Editors). (2019). Phage Therapy: A Practical Approach. Springer International Publishing 3. Hyman P. and Abedon S. T. Editors. (2012). Bacteriophages in Health and Disease. Volume 24 of Advances in molecular and cellular microbiology. Contributor C.A.B. International. Edition- illustrated. Publisher CABI. 4. Kutter E. and Sulakvelidze A. Editors. (2005). Bacteriophage Therapy in Humans. Chapter 14. Bacteriophages, biology and applications. CRC Press. 5. Principi N., Silvestri E. and Esposito S. (2019). Advantages and Limitations of Bacteriophages for the Treatment of Bacterial Infections. Front. Pharmacol. 10: 513 6. Vázquez R., García E. and García P. (2018). Phage lysins for fighting bacterial respiratory infections: a new generation of antimicrobials. Minireview article. Front. Immunol. 9: 2252
	C. Mycoviruses: A new dimension in Microbiology 1. Abbas J. (2016) A review Paper Mycoviruses Journal of Plant Pathology and Microbiology 2. Abid M., Khan M. Mushtaq. S., Afzaal S., and Haider M. (2018). A comprehensive review on mycoviruses as biological control agent. World 3. Journal of Biology and Biotechnology, 3(2): 187-192. 4. Kondo H., Chiba S., Toyoda K. and Suzuki N. (2013). Evidence fornegative-strand RNA virus infection in fungi. Virology, 435: 201–209 5. Niu Y., Yongze Yuan Y., Mao J., Yang Z., Cao Q., Zhang T., Wang S. and Liu D. (2018) Characterization of two novel mycoviruses from *Penicillium digitatum* and the related fungicide resistance analysis. Scientific Reports. 8: 5513 6. Zoll J., Verweij P. E. and Melchers W. J. G. (2018): Discovery and characterization of novel *Aspergillus fumigatus* mycoviruses. PLoS ONE 13(7): e0200511.
	D. Introduction of algal viruses 1. Coy S. R., Gann E. R., Pound H. L., Short S. M. and Wilhelm S. W. (2018). Viruses of eukaryotic algae: Diversity, Methods for detection and future directions. Viruses. 10 (9): 487

Semester III

23-MBEP-237: Clinical Microbiology & Virus Technology

Choice based Optional Practical Paper (Elective)
(Total Workload): - 2 credits x 30 hrs = 60 hrs in semester

Course outcomes:

Students will be able to

CO1: Perform isolation, purification and preservation of bacteriophages
CO2: Test various concepts of bacteriophage growth kinetics
CO3: Demonstrate applications of bacteriophages

Unit	Title and Contents	Lectures
I	A. Isolation and purification of lytic bacteriophages from various environmental samples (Phages specific for E. coli /Salmonella SPP./Klebsiella Spp.). B. Isolation and enumeration of actinophages from soil sample C. Isolation of phyco viruses from various sources in nature D. Determination of Adsorption Rate Constant for phage and One step growth Curve Experiment	30
II	A. Negative staining (Sample preparation) for electron microscopicstudies (Demonstration) B. Biocontrol of any plant pathogen using plant Bioassay technique C. In-vitro use of lytic bacteriophages specific against *Klebsiella* spp.biofilm (Micro- titre plate experiment) D. In-vitro use of lytic bacteriophages for decontamination of watersample (Microcosm Studies). E. Bacteriophage Formulation technique-Carrier based phage formulation and their shelf-life study(3 months)	30

Suggested References 23-MBEP: 237 Practicals based on Clinical Microbiology & Microbial Virus Technology Semester III	
Unit	**References**
I	1. Ackerman H. W. (2009). Phage classification and characterization. In: Clokie MRJ, Kropinski AM (Eds) Bacteriophages: methods and protocols, Volume: Isolation, characterization and interactions, Vol. 501. Humana Press, New York. 2. Ahiwale S. (2013). Bacteriophages against enteric bacterial pathogens and their potential for bioremediation of pathogen infested water bodies PhD thesis, University of Pune,Pune, Maharashtra. 3. Marei E.M. and Elbaz R. M. (2013) Isolation and molecular characterization of three virulent actinophages specific for S*treptomyces flavovirens*. Journal of Virology Research. 2(1): 12-17 4. Coy S. R., Gann E. R., Pound H. L., Short S. M. and Wilhelm S. W. (2018). Viruses of eukaryotic algae: Diversity, Methods for detection and future directions. Viruses.10: 487. 5. Lanning S. and Williams S.T. (1982). Methods for the direct isolation and enumeration of Actinophages in soil. Journal of General Microbiology, 128: 2063-2071 6. Nabergoj D., Modic P. and Podgornik A. (2018). Effect of bacterial growth rate on bacteriophage population growth rate. Microbiology Open, 7, e00558.
II	1. AhiwaleS.S. (2011). *InVitro* management of hospital Pseudomonas *aeruginosa* biofilm using indigenous T7-like lytic phage. Curr. Microbiology.62: 335-340 2. Balan A. and Padilla G. (1997). New thermal inducible phages isolated from tropical soils. Brazilian Journal of Genetics. 20: 4 3. Ahiwale S. (2013) Bacteriophages against enteric bacterial pathogens and their potential for bioremediation of pathogen infested water bodies PhD thesis, University of Pune, Pune, Maharashtra. 4. McLaughlin M.R. and Brooks J.P. (2008). EPA worst case water microcosms for testing phage biocontrol of *Salmonella*. J Environ Qual. 37: 266-271 5. Umrao P. D., Kumar V. and Kaistha S. D. (2021). Biocontrol potential of bacteriophage -sp1 against bacterial wilt-causing Ralstonia solanacearum in Solanaceae crops Egyptian Journal of Biological Pest Control 31:61 https://doi.org/10.1186/s41938-021-00408-3 6. Vinod M. G., Shiva M. M., Umesha K. R., Rajaveera B. C., Krohne G. and Karunasagar J. (2006). Isolation of *Vibrio harveyi* bacteriophage withpotential for biocontrol of luminous vibriosis in hatchery environments. Aquaculture. 55: 117-124

Semester IV

23- MBCT-241: Pharmaceutical Microbiology

Core Compulsory Theory Paper

[4 Credits; 60 Lectures]

[1 credit=15 hrs x 60 mins]

Corse outcomes:

Students will be able to:

CO1: Explain the concept of Medicinal Chemistry, historical perspectives of drug discovery as well as the modern rational approach along with classification of drugs.

CO2: Give account of the various stages of drug development process and the tools/techniques used at every stage.

CO3: Describe the regulatory authorities functional in the drug development process and explain roles of each of them and importance of pharmacopeia with various example of drug formulations.

CO4: Describe the Pharmacokinetics and the mechanism of ADME

Unit	Title and Contents	Lectures
I	**General introduction to medicinal chemistry** A. Definition and explanation of terms used in medicinal chemistry (HITS, Lead compound, Toxicity studies, HTS, ADME). Nomenclature of drugs B. Historical perspectives, significance of medicinal chemistry C. Introduction to modern drug discovery, rational drug design, molecular modeling, gene and DNA technology in chemotherapy D. Classification of drugs based on therapeutic classes, target, mechanism of action, chemistry, etc.	15
II	**Drug development** A. Lead optimization: lead likeness, drug likeness, determination of biological, biochemical properties of drug, pharmacovigilance. B. Drug designing: Ligand based receptor based drug design. (Protein Crystallography, molecular docking) C. Drug development: Preclinical development. Toxicity testing – acute,sub-acute, chronic. D. Clinical development: Clinical trials (aims, objectives and conduct). Clinical trials I, II, III and IV.	15

III	**Biopharmaceuticals: Regulations and sources** A. Regulatory authorities and its role: FDA, WHO and CLSI B. Introduction to pharmacopeia: IP, USP, and BP C. Formulation of following pharmaceutical preparation as per IP: i. Antibiotics (with any one example) ii. Antipyretics (with any one example) iii. Steroids (with any one example) iv. Injectables (Distilled water, Saline) v. Vitamins (with any one example	15
IV	**Physicochemical properties of drug and drug metabolism** A. Passage of molecules through biological barriers. Membrane transport (paracellular, transcellular). B. Drug absorption: Drug dosages, from gastric emptying to gastric permeability to drug, first pass effect, Bioavailability. C. Drug distribution: Drug-plasma/ serum binding, blood brain barrier, accumulations in tissues. D. Drug elimination: Drug excretion, Drug biotransformation Biotransformation reactions, Functionalization, Conjugation reaction, Reactions leading to toxic metabolites	15

Suggested References 23-MBCT-241: Pharmaceutical Microbiology-Semester IV Core Compulsory Theory Paper	
Unit	**References**
I	**General introduction to medicinal chemistry** 1. Agarwal S. S. and Paridhavi M. (2007). Herbal drug technology. Universities Press(India) Pvt. Ltd 2. Altreuter D. and Clark D. S. (1999) Combinatorial Biocatalysis: Taking the lead from nature. Curr. Opin. Biotechnol. 10: 130-136 3. Burn J. H. (1957) Principles of Therapeutics. Blackwell Scientific Pub. O. Ltd.Oxford. 4. Chatwal G. P. (2003) Bio-pharmaceutics and Pharmacokinetics. Himalaya Publishing House, Mumbai. 5. Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA). www.cpcsea.com 6. Dewick P. M. (2002). Medicinal natural products: A biosynthetic approach, 2nd Ed., John Wiley and Sons 7. Erhardt P. W. (2006). Medicinal Chemistry in the New Millennium: A Glance into the Future, Ed. Chorghade M. S. in Drug discovery and Development Volume I: Drug Discovery. Wiley-Interscience, John Wiley and Sons Inc. USA. 17-102. 8. Graly J. O. and Joubert P.H. (1997). Handbook of Phase I /II clinical drug trials, CRC Press 9. Iyengar M. A. (1993). Pharmacology of Powdered Crude Drugs. Iyengar series. Manipal, India 10. Micheles P. S., Khmelnitsley Y. L., Dordick J. S. and Clark D. S. (1998). Combinatorial biocatalysis, a natural approach to drug discovery. Trends in Biotechnol. 16(5): 210-215 11. Rawlins E. A., (Ed). (2002). Bentley's Textbook of Pharmaceutics. 8th Ed. Bailliere Tindall, London 12. Satoskar R. S. and Bhandarkar S. D. (1991). Pharmacology and Pharmacotherapeutics. 12th Ed., Vol. 1 and 2. Popular Prakashan, Mumbai. 13. Vyas S. P and Dixit V. R. (2002). Pharmaceutical Biotechnology, CBS Publishers and Distributors, New Delhi
II	**Drug development** 1. Franklin T. J. and Snow G. A. (1975). Biochemistry of Antimicrobial Action. Chapman and Hall, London. 1-22 and 160-174 2. 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. 3. Goldstein A., Aronow L., and Kalman S. M. (1969). Principles of Drug Action. The Basis of Pharmacology. Harper international edition New York. 4. Lorian V. (1986). Antibiotics in laboratory medicine. 2nd Ed. Williams & Wilkins Publication 5. National Committee for Clinical Laboratory Standards (now Clinical and Laboratory Standards Institute, CLSI). NCCLS: 1997. Methods for dilution

	antimicrobial susceptibility testing for bacteria that grows aerobically. Approved Standards M7-A4. Villanova, PA: 6. National Committee for Clinical Laboratory Standards (now Clinical and Laboratory Standards Institute, CLSI). NCCLS: 2002.Performance standards for antimicrobial susceptibility testing; 12th information supplement (M100- S1). Villanova, PA
III	**Biopharmaceuticals: Regulations and sources** 1. Blondelle S. E., Perez Paya E. and Houghten R. A. (1996). Synthetic Combinatorial Libraries: Novel Discovery Strategy for Identification of Antimicrobial Agents. Antimicrobial Agents and Chemotherapy. 1067–1071 2. Holliger M. A. (2008). Introduction to Pharmacology. 3rd Ed. CRC Press. Taylor and Francis. 3. Indian Pharmacopoeia (IP 2018). 8th Edition. Four Volumes with addendum 2019. Published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health and Family Welfare. 4. Kokate C. K., Purohit A. P., Gokhale A. B. (2000). Pharmacology. 4th Ed., Nirali Prakashan. 5. Micheles P. S., Khmelnitsley Y. L., Dordick J. S. and Clark D. S. (1998). Combinatorial biocatalysis, a natural approach to drug discovery. Trends in Biotechnol. 16(5): 210-215 6. Osol A. (1980). Remington's Pharmaceutical Sciences, 16th Ed., Easton, Pennsylvania: Mack Publishing Company. 7. Satoskar R. S. and S. D. Bhandarkar (1991). Pharmacology and Pharmacotherapeutics. 12th Edition. Vol. 1 and 2. Popular Prakashan, Mumbai. 8. Vyas S. P. and Dixit V. R. (2002). Pharmaceutical Biotechnology. CBS Publishers and Distributors, New Delhi 9. Walsh G. (2006). Biopharmaceuticals: Biochemistry and Biotechnology. 2nd edition. Wiley (E-Book, 2013).
IV	**Physicochemical properties of drug and drugmetabolism** 1. Holliger M. A. (2008). Introduction to Pharmacology. 3rd Ed. CRC Press. Taylor and Francis. 2. Kokate C. K., Purohit A. P., Gokhale A. B. (2000). Pharmacology. 4th Ed. Nirali Prakashan. 3. Micheles P. S., Khmelnitsley Y. L., Dordick J. S. and Clark D. S. (1998). Combinatorial biocatalysis. A natural approach to drug discovery. Trends in biotechnol. 16(5): 210-215

Semester IV

23-MBCT-242: Microbial Technology

Core Compulsory Theory Paper

[4 Credits; 60 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:

Students will be able to:

CO1: Describe basic operational parameters of different fermenters and reactors design

CO2: Explain about governing and influencing factors for any fermentation process

CO3: Explain about significance and features of batch, continuous and fed-batch operation mechanisms

CO4: Apply knowledge regarding designing part of aeration, agitation assembly as well as designs of fermenter reactors

CO5: Describe the significance of Intellectual property rights (IPR), different types and categorization of IP's as well as pros and cons of legal aspects of IPR

Unit	Title and Contents	Lectures
I	**Bioreactor design and operation** A. Designing of bioreactors Design aspects CSTRs: The dimensional ratios of the outer shell, and the operational aspects such as working volume, baffles and impellers. B. The configuration (placement) of impellers in a vessel and the different types of impellers (types of turbines and propellers, and their combinations) C. Immobilized cell reactors and air-lift reactors–Design and operation. D. Batch, Fed-batch and Continuous operation: Applications,advantages and limitations of each type	15
II	**Process Variables and Monitoring** **A. Process Variables**: i. Aeration Theory of oxygen transfer in bubble aeration, Oxygen transfer kinetics (Oxygen Uptake Rate –OUR; Oxygen Transfer Rate OTR;Ccrit), determination of KLa. ii. Agitation Functions of agitation. Flow patterns with different types of impellers. a) Fermentation broth rheology and power requirements for agitation – Concept of Newtonian and non-Newtonian fluids, b) Effect of broth rheology on heat, nutrient and oxygen transfer, Reynold's number, Power number, Aeration number: working out examples using different software c) Reynolds number ,Power number ,Aeration number: working out examples using different software	15

	B. Monitoring of process variables: i. Use of various types of sensors and biosensors for monitoring environmental parameters (pressure, pH, temperature, DO and DCO2) ii. Basic principles of operation, types of biosensors	15
III	**Microbial Fermentation Processes:** Upstream, Fermentation and Downstream Processing for the following: i. Antibiotics (Rifamycin) ii. Microbial enzymes (Chitinase) iii. Exopolysaccharides (Pullulan) iv. Use of immobilized cells / enzymes for bioconversion v. Use of fungi in agriculture and environmental applications	15
IV	**Principle Concepts of IPR, ISO & Validation Process:** A. Intellectual Property Rights (IPR): i. Basic concepts of IPR ii. Introduction to forms of IPR – Patents and Designs B. The concept of ISO Certification. C. Preparation of SOPs D. Validation protocols for methods in: i. Quality Control ii. Process validation The above should be discussed within WHO Norms. Exercises on preparation of SOPs, operation and validation for analytical methods	15

Suggested References 23-MBCT 242: Microbial Technology Semester IVCore Compulsory Theory Paper

Unit	References
I	**Bioreactor design and operation** 1. BIOTOL series. (1992). Bioreactor Design and Product Yield. Butterworth Heinemann. 2. Doran P. M. (1995). Bioprocess Engineering Principles. Imprint-AcademicPress. Copyright-Elsevier. 3. Lydersen B. K., D'Elia N. A. and Nelson K. M. (Eds.) (1993). Bioprocess Engineering: Systems, Equipment and Facilities. John Wiley and Sons Inc. 4. Maiti B. R. (2018). Principles of Bioreactor Design. Publisher: Viva books 5. McDuffie N. G. (1991). Bioreactor Design Fundamentals 1st Edition, Elsevier: eBook ISBN: 9781483221083 6. Ratledge C. and Kristiansen B. eds. (2001). Basic Biotechnology. 2nd Ed. Cambridge Univ. Press. Cambridge 7. Singh L., Mahapatra D. and Yousuf A. (2019). Bioreactors: Sustainable Design and Industrial Applications in mitigation of GHG emissions. Elsevier. ISBN-0128212640, 9780128212646

II	**Process Variables and Monitoring** 1. Aiba S., Humphrey A. E. and Millis N. F. (1982). Biochemical Engineering. Second Edition. Academic Press. 2. Chand S. (1998). Fermentation Biotechnology: Industrial Perspectives. Industrial Perspectives: Proceedings of the Symposium on Biotech Industry - a Challenge for 2005 A.D. -with Special Reference to Fermentations. November4-6, 1998. Publisher: All India Biotech Association 3. Jozala A. F. (2017). Fermentation Processes. Publisher-BoD. Books on Demand. ISBN-9535129279, E-Book 9789535129271 4. Mandenius C-F. (2016). Bioreactors: Design, Operation and Novel Applications. Reprint. Publisher-John Wiley & Sons. ISBN 3527683372 E- Book- 9783527683376 5. Larroche C., Sanroman M., Du G. and Pandey A. (Editors). (2016). Current Developments in Biotechnology and Bioengineering: Bioprocesses, Bioreactors and Controls. Publisher-Elsevier, ISBN 0444636749,E–Book 9780444636744 6. Lydersen B. K., D' Elia N. A. and Nelson K. M. (Eds.) (1993) Bioprocess Engineering: Systems, Equipment and Facilities. John Wiley and Sons Inc. 7. BIOTOL series. (1992). Operational Modes of Bioreactors Butterworths – Heinemann. 8. Stanbury P., Whitaker A. and Hall S. (2016). Principles of Fermentation Technology. 3rd Edition Imprint: Butterworth-Heinemann
III	**Microbial Fermentation Processes:** 1. Arora D. K. (2005). Fungal Biotechnology in Agricultural, Food and Environmental Applications (Mycology), Marcel Dekker, Inc. New York. Basel 2. Belter P. A., Cussler E. L. and Hu W. S. (1994). Bioseparations Downstream processing for Biotechnology. John Wiley and Sons. N.Y. ISBN: 978-0- 471-12113-8 3. Crueger W. and Crueger A (1990). Biotechnology: A textbook of Industrial Microbiology. 2nd edition. Sinauer associates, Inc 4. Klegerman M. E. and Groves M. J. (1992). Pharmaceutical Biotechnology: Fundamentals and Essentials. Interpharm Press Ltd. Buffalo Grove, Illinois 5. Meshram S. U. and Shinde G. B. (2009). Applied Biotechnology. I.K. International Pvt. Ltd. 6. Mishra C. S. K. (Editor) and Pascale Champagne (Associate editor). (2009). Biotechnology applications. I. K. International Pvt. Ltd. 7. Peppler H. J. and Perlman D. (1970). Microbial Technology. Volume 1and 2. Academic Press, New York. 8. Ponkhshe S. (1988). Management of Intellectual Property, Bhate and Ponkhshe Prakasham, Pune 9. Reed G. (Editor). Prescott and Dunn's Industrial Microbiology. 4th Ed., CBSPub. New Delhi. 10. Van Damme E. J. (1984.) Biotechnology of Industrial Antibiotics. Marcel Dekker Inc., New York.

	11. Wiseman A. (1985). Topics in Enzyme and Fermentation Biotechnology.Vol. 1and 2. John Wiley and Sons, New York
IV	**Principle concepts of IPR, ISO and Validation Process:** 1. Calnan N., Redmond A. and O'Neill S. (2009). The FDA's draft process validation Guidance A perspective from industry. Process Validation Guidance. Pharmaceutical Engineering. GMP Publishing. 7(4): 1-17 2. Supplementary Training Modules on Good Manufacturing Practice. Validation WHO Technical Report Series, No.937, 2006, Annex 4.

Semester IV

23- MBCT- 243: Dissertation

Course outcomes:

CO1: Identify the problem area to carry out research and state the hypothesis through survey of scientific literatureobtained from authentic sources/ means.
CO2: Decide the line of action, describe methodology and accordingly design experimental set up
CO3: Record observations, statistically analyze the obtained data, effectively represent and interpret the data and finally drawing conclusions.
CO4: Write an extensive and comprehensive report of research work so as to convey dissertation in the mostproficient and effective way

Guidelines for 23-MBCT- 243
Semester IV: Dissertation

1. A dissertation can be carried out by a single student or by group of students where the group should not contain more than four students.
2. The dissertation report will be prepared as per the thesis format.
3. Submission of the dissertation report will be at least ten days before the date of examination.
4. One copy of the report will be preserved in the department, in college.
5. If there are more than one student carrying out a single dissertation, a single report can be submitted to the department and these students will be assessed based on single oral presentation.
6. In such case, presentation should be carried out by all the students carrying out the same work; dividing the presentation equally among them.
7. At the time of presentation, the external and internal examiners appointed by the university will be present; the dissertation guide may or may not be present.
8. Presentation should be carried out to in the presence an audience comprising of examiners appointed by the university, departmental teaching staff and the postgraduate students of the department (M.Sc. I and II).
9. Oral presentation can be carried out using posters, blackboard, transparencies, model or LCD projector.
10. The allotted time for each oral presentation (one project) should be 10 to 12 minutes, followed by question and answer session of 5 to 8 minutes. The audience can participate in this session.
11. **The assessment of the dissertation is for total of 100 marks (IA-30 and UA-70).**
12. The assessment of first 30 marks (in semester) will be carried out by the guide(s) who has supervised the work of the candidate(s) throughout the semester. The assessment will be carried out on the basis of the points, as per the accompanied format of the mark sheet. Head of the department should communicate this point wise assessment system to the dissertation supervisor, well in advance. Guide(s) will give appropriate marks, point-wise and submit it in a sealed envelope(s) to the Head of the respective department, three days prior to examination and project presentation. On the day of examination, Head of the department will hand over these unopened envelopes to the examiners.

13. Assessment of remaining 70 marks (end semester examination for both courses) will becarried out for individual student at the time of examination jointly by Internal and External examiners by the means of oral presentation. The assessment will be carried out on the basis of the points as per the accompanied format of the mark sheet.
14. Students should be made aware of the assessment parameters, on which they will be assessed throughout the semester and at the end of the fourth semester.

Note: The external and internal examiners by mutual agreement will appropriately settle the marks given by the guide (reconsider, if necessary) and marks of oral presentation, and submit the mark list to the Coordinator of the M. Sc. Examination Panel for that examination.

Semester IV

23-MBET-244: Quality Assurance and Validation in Pharmaceutical Industry and Development of Anti-Infectives

Choice based Optional Theory Paper (Elective)

[2 Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:

Students will be able to –

CO1: Explain GMP, GLP and safety measures.CO2: Explain the principles of Bioethics.

CO3: Describe the importance, role and functions of various regulatorycommittees on biosafety.

CO4: Describe the importance, role and functions of various regulatorycommittees on quality control and quality assurance.

Unit	Title and Contents	Lectures
I	**Quality Assurance and Validation in Pharmaceutical Industry** A. Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) in pharmaceutical industry. Quality assurance and quality management in pharmaceuticals ISO, WHO and US certification. Safety in microbiology laboratory. B. Safety profile of drugs: i. Sterility Testing ii. Pyrogenicity testing iii. Mutagenicity and Carcinogenicity testing iv. Teratogenicity testing	**15**
II	**Development of Anti infectives:** Therapeutic ratio, MIC and MBCSusceptibility Testing: A. Use of liquid and solid media B. Factors affecting susceptibility testing, CLSI guidelines C. Diffusion methods – agar dilution technique, gradient plate techniques-test, Kirby Bauer, Stokes method D. Susceptibility testing for: i. Anti-mycobacterial agents ii. Anti-fungal agents iii. Anti-protozoan agents iv. Anti-viral agents	**15**

Suggested References 23-MBET-244: Semester IV
Quality Assurance and Validation in Pharmaceutical Industry and Development of Anti-Infectives
Choice based Optional Theory Paper (Elective)

Unit	References
I	1. Blondelle S. E., Pérez-Payá E. and Houghten R. A. (1996). Synthetic combinatorial libraries: novel discovery strategy for identification of antimicrobial agents. Antimicrobial Agents and Chemotherapy. 1067–1071 2. Holliger M. A. (2008). Introduction to Pharmacology. Third Ed., CRC Press. ISBN9781420047417 3. Kokate C. K., Purohit A. P. and Gokhale A. B. (2000). Pharmacology, 4th Edition. Nirali Prakashan. 4. Maron D. M. and Bruce N. A. (1983). Revised methods for the Salmonella mutagenicity test. Mutation Research. 113: 173-215 5. Osol A. and Hoover J. E. (1975). Remington's Pharmaceutical Sciences, 15th Ed., MackPub. Co., Pennsylvania. 6. Vyas S. P and Dixit V. R. (2002). Pharmaceutical Biotechnology, CBS Publishers and Distributors, New Delhi
II	1. Franklin T. J. and Snow G. A. (1975). Biochemistry of Antimicrobial Action. Chapman and Hall, London. 1-22 and 161-200. 2. 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 3. Goldstein A., Aronow L., and Kalman S. M. (1969) Principles of Drug Action, The Basis of Pharmacology, Harper international edition New York. 4. Lorian V. (1986). Antibiotics in laboratory medicine. 2nd Ed, Williams & Wilkins Publication 5. National Committee for Clinical Laboratory Standards (now Clinical and Laboratory Standards Institute, CLSI). NCCLS: 1997. Methods for dilution antimicrobial susceptibility testing for bacteria that grows aerobically. Approved Standards M7-A4. Villanova, PA. 6. National Committee for Clinical Laboratory Standards (now Clinical and Laboratory Standards Institute, CLSI). NCCLS: 2002. Performance standards for antimicrobial susceptibility testing; 12th information Supplement (M100-S1). Villanova, PA

Semester IV

23-MBEP-244: Practicals based on Quality Assurance and Validation in Pharmaceutical Industry and Development of Anti Infectives

Choice based Optional Practical Paper (Elective)
(Total Workload): - 2 credits x 30 hrs = 60 hrs in semester

Course Outcomes:

Students will be able to –

CO1: Describe the NABL norms for calibration of Autoclave and Laminar Air Flow.

CO2: Refer to FSSAI manuals to demonstrate its application in water and food testing, tests prescribed for different samples for detection of different contaminating pathogens

CO3: Carry out quality assessment of packed foods with respect to pathogens like L monocytogenes.

Unit	Title and Contents	Lectures
I	**Sterility testing of following pharmaceutical preparations as per IP:** i. Oral preparation: Antipyretic or antibiotic tablets ii. Liquid preparation: water soluble vitamin or cough syrup orophthalmic drops iii. Bulk preparation: (any two) Surgical Cotton rolls/ gauze/ surgicalsutures/ disposable syringes.	30
II	**Detection and isolation of anti-infectives from plant** i. Extraction of bioactive principles from plant and activityfractionation ii. Estimation of its antimicrobial activity using standard guidelines(CLSI)	30

Suggested References 23- MBEP-244: Semester IV

Practicals based on Quality Assurance and Validation in Pharmaceutical Industryand Development of Anti Infectives from plants

Choice based Optional Practical Paper(Elective)

Unit	References
I	**Sterility testing of following pharmaceutical preparations as per IP** 1. Holliger M. A. (2008). Introduction to pharmacology. 3rd Edition. CRCPress 38 2. Indian Pharmacopoeia. (2007). Government of India, Ministry of Health and Family Welfare. The Indian Pharmacopoeia commission. Ghaziabad.1:53 3. Knudsen L. F. (1949). Sample size of parenteral solutions for sterilitytesting. JAmer Pharm Assoc. 38: 332–337. 4. McGuire J. and Kupiec T.C. (2007). Quality-control analytical methods: thequality of sterility testing. Intl J Pharm Compounding. 11(1): 52–55. 5. Madsen R. E. (1994). US vs. Barr Laboratories: a technical perspective.PDA JPharm Sci Tech. 48(4): 176–179. 6. Moldenhauer J. and Sutton S.V.W. (2004). Towards an improved sterilitytest.PDA J Pharm Sci Tech. 58 (6): 284–286. 7. Moldenhauer J. (2006). Viability-based rapid microbiological methods forsterility testing and the need for identification of contamination. PDA J PharmsciTech. 60(2):81-88 8. Schroeder H. G. (2005). Sterility failure analysis. PDA J Pharm Sci Tech.59(2):89–95. 9. Sykes G. (1956). The technique of sterility testing. J Pharm Pharmacol. 8:573
II	**Detection and isolation of anti infectives from plant** 1. Lorian V. (1986). Antibiotics in laboratory medicine. 2nd Ed. Williams and Wilkins Publication 2. National Committee for Clinical Laboratory Standards (now Clinical and Laboratory Standards Institute, CLSI). NCCLS: 1997. Methods for dilution antimicrobial susceptibility testing for bacteria that grows aerobically. Approved Standards M7-A4.Villanova, PA. 3. National Committee for Clinical Laboratory Standards (now Clinical and Laboratory Standards Institute, CLSI). NCCLS: 2002. Performance standards for antimicrobial susceptibility testing; 12th information supplement (M100-S1). Villanova, PA.

Semester IV

23- MBET-245: Advances in Microbial Technology

Choice based Optional Theory Paper (Elective)

[2Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course outcomes

Students will be able to

CO1: Describe advances in Microbial Technology,
CO2: Explain applications of animal cell culture technology.

Unit	Title and Contents	Lectures
I	Microbial Growth characteristics and product formation i. Concept of primary (growth associated) and secondary (growth on associated) metabolites and their control, ii. Kinetics of growth and product formation (growth rate, yield coefficient, efficiency etc.) iii. Effect of type of growth on fermentation: The type of growth (mycelia pellet form, mycelia filamentous form, free cell, cells producing exopolysaccharides) affects mass transfer of nutrients, oxygen and heat; as also cell proliferation can be affected by shearing of cells. At least one example of each type may be explained to show these effects in any suitable fermentation.	15
II	i. Animal cell culture technology to produce: ii. Recombinant forms of natural proteins (insulin, erythropoietin), iii. Recombinant vaccines (protein: HIV, hepatitis B and DNA: HIV, malaria), Recombinant enzymes (lipase, restriction endonuclease), iv. Monoclonal antibodies v. Nucleic acid based products (introduction to gene therapy	15

Suggested References23- MBET -245: Advances in Microbial Technology Semester IV Choice based Optional Theory Paper (Elective)	
Unit	**References**
I	1. Gupta V. K., Schmoll M., Maki M., Tuohy M. and Mazutt M. A (Editors).(2013) Applications of Microbial Engineering. CRC Press 2. Rao D. G., (2010) Introduction to Biochemical Engineering. Tata McgrawHill Education 3. Stanbury P. F. (2009) Principles of Fermentation Technology. 2 Edition.Elsevier (A Division of Reed Elsevier India Pvt. Limited).
II	1. Moo Young M. ed. (1985). Comprehensive Biotechnology Vol: III and IV,Pergamon Press. N. Y 2. Ratledge C. and Kristiansen B. (editors). (2001) Basic Biotechnology. 2nd Ed.Cambridge Univ. Press. Cambridge 3. Satyanarayana U. (2005). Biotechnology. Books and Allied (p) limited.

23-MBEP-245 Practicals based on Advances in Microbial Technology Semester IV
Choice based Optional Practical Paper (Elective)
(Total Workload): - 2 credits x 30 hrs = 60 hrs in semester

Course outcomes:

Students will be able to

CO1: Describe Advances in Microbial Technology.
CO2: Explain applications of animal cell culture technology.
CO3: Explain latest techniques and their applications.

Unit	Title and Contents	Lectures
I	**A Bioconversion** Bioconversions using immobilized systems (cells / enzyme)Parameter testing: i. Effect of gel concentration **ii.** Effect of cell / enzyme concentration **B. Laboratory scale production** Laboratory scale production and media optimization for:exopolysaccharide / bioemulsifier production	30
II	**Animal Cell Culture Technology** A. Preparation of Hybridoma from tumour cell lines. B. Production of monoclonal antibodies from hybridoma of tumourcell lines	30

Suggested References 23- MBEP- 245: Semester IV Practicals based on Advances in Microbial TechnologyChoice based Optional Practical Paper(Elective)	
Unit	**References**
I	**A. Bioconversion:** 1. Arana-Peña S., Rios N. S., Carballares D., Mendez-Sanchez C., Lokha Y., Gonçalves L. and Fernandez-Lafuente R. (2020). Effects of enzyme loading and immobilization conditions on the catalytic features of lipase from *Pseudomonas fluorescens* immobilized on octyl-agarose beads. Frontiers in bioengineering and biotechnology. 8: 36. 2. Brena B, González-Pombo P and Batista-Viera F. (2013). Immobilization of enzymes: a literature survey. Methods Mol Biol. 1051: 15-31. 3. Gedam P. S., Raut A. N. and Dhamole P. B. (2019). Effect of operating conditions and immobilization on butanol enhancement in an extractive fermentation using non-ionic surfactant. Appl Biochem Biotechnol. 187: 1424–1436 4. Mahajan R., Gupta V. K. and Sharma J. (2010). Comparison and suitability of gel matrix for entrapping higher content of enzymes for commercial applications. Indian J Pharm Sci. 72(2): 223-228.

	B. **Laboratory scale production** 1. Biswas J. and PaulA. K. (2017). Optimization of factors influencing exopolysaccharide production by *Halomonas xianhensis* SUR308 under batch culture. AIMS Microbiology, 3(3): 564–579. 2. Hereher F., El-fallal A. and Abou-Dobara M. (2018). Cultural optimization of a new exopolysaccharide producer. "*Micrococcus roseus*". Beni-Suef University Journal of Basic and Applied Sciences. 7(4): 632-639

Semester IV

23-MBET-246: Industrial waste water treatment and Industrial production of vaccines

Choice based Optional Theory Paper (Elective)

[2 Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course Outcomes:

Students will be able to

CO1: Know the concepts of Industrial Waste Water Treatment and sludge treatment

CO2: Explain Industrial Production of Vaccines

Unit	Title and Contents	Lectures
I	A. **Concept and Introduction** to Primary, Secondary and Tertiary treatment of Wastewater. B. **Biological Treatment**- Aerobic and Anaerobic, Suspended and Attached growth processes. C. Activated Sludge treatment and analysis (reactions and Kinetics, mass balance analysis, Hydraulic characters) Critical Operating parameters like DO, Hydraulic retention time, Mean cell retention time, F/M ratio. D. **Current industrial wastewater treatment processes:** Composition, physico-chemical properties and various effluents treatment methods with reference to: i. Dairies ii. Food processing iii. Dyeing industry / Dye-house effluents iv. Paper and pulp industry: Effluent Disposal and Reuse	15

II	**Industrial production of vaccines** **A. Introduction to vaccines** **B. Types**: Inactivated, Attenuated, Toxoid, Subunit, Conjugate, Experimental,Valence, Heterotypic **C. Production** i. Pilot and Industrial scale production ii. Excipients iii. Role of Adjuvants and preservatives **D. Production of viral, bacterial and protozoal vaccines** – Generations of vaccines: i. First generation vaccines– Live attenuated (BCG, MMR) and Inactivated (Pertussis, Tetanus toxoids) ii. Second generation vaccines(synthetic) protein/ peptide/ polysaccharide) a. Subunit vaccines (Hep B) b. Recombinant (Rotavirus), Hapten-Conjugate vaccines (diphtheria) iii. Third generation vaccines – DNA/RNA and Idiotype vaccines(Malaria) iv. Next generation vaccines using OMICs approach: SARS.	15

23-MBET 246: Semester IV

Industrial waste water treatment and Industrial production of vaccinesChoice based Optional Theory Paper (Elective)

Unit	References
I	1. Abdallh M. N., Abdelhalim W. S. and Abdelhalim H. S. (2016). Industrial wastewater treatment of food industry using best techniques. International Journal of Engineering Science Invention, 5(8): 15-28. 2. Ali Z. and Rahman M. (2008) Physico-chemical characteristics of pulp and paper mill effluent. Research in Environment and Life Sciences.1 (2): 59-60. 3. Ashtekar S., Bhandari V. M., Shirsath S. R., Sai Chandra P. L. V. N. and Jolhe P. D. (2013). Dye wastewater treatment: removal of reactive dyes using inorganic and organic coagulants. Journal of Industrial Pollution Control, 30(1): 33-42 4. Bajpai P. and Bajpai P. K. (1994). Mini review: Biological color removal of pulp and paper mill wastewaters. Journal of Biotechnology. 33: 211-220. 5. Bajpai P. (2001). Microbial degradation of pollutants in pulp mill effluents. Advances in Applied Microbiology.48: 79-134. 6. Catalkaya E.C. and Kargi F. (2006). Color, TOC and AOX removals from pulp mill effluent by advanced oxidation processes: A Comparative Study. Journal of Hazardous Materials. 139 (2): 244-253 7. Metcalf and Eddy (Eds.). (1991). 3rd Edition, Tata Mac Graw Hill Publishing Co. Ltd. New Delhi. 8. Patwardhan A. D. (2008). Industrial wastewater treatment. © Prentice – Hall ofIndia

	Pvt. Ltd., New Delhi. ISBN 978-81-203-335 9. Tchobanoglous G. and Burton F. L. (1991) Wastewater engineering, treatment,disposal and reuse. 3rd Edition, Metcalf and Eddy (Eds.), Tata Mac Graw Hill Publishing Co. Ltd. New Delhi.
II	1. Casida L. E. (1984). Industrial Microbiology.Wiley Easterbs, New Delhi 2. Patel A. H. (1985). Industrial Microbiology, Macmillan India Ltd. 3. Soma Marla S., Bonthala V. S., München H. Z., Suresh., Gaur V. S. and Gohar Taj G. (2012). Biotechnology in Medicine and Agriculture Principles and Practices. Publisher: I.K International Publishing House pvt.ltd, Editors: Anil Kumar, Ashwani Pareek, and Sanjay Mohan Gupta. 739-759 4. Stanbury P. F. and Whittaker A. (1984). Principles of Fermentation Technology. Pergamon press. 5. https://www.slideshare.net/adammbbs/pathogenesis-3-rd-internal-updated-43458567 6. https://www.bio.fiocruz.br/en/images/stories/pdfs/mpti/2013/selecao/vaccine-process-technology.pdf 7. https://www.dcvmn.org/IMG/pdf/ge_healthcare_dcvmn_introduction_to_pd_for _vaccine_ production_29256323aa_10mar2017.pdf 8. https://www.sciencedirect.com/science/article/pii/B9780128021743000059 https://www.researchgate.net/publication/313470959_Vaccine_Scale- up and Manufacturing

Semester IV

23-MBEP 246: Practicals based on Industrial Waste Water Treatment and Industrial Production of Vaccines

Choice based Optional Practical Paper (Elective)

(Total Workload): - 2 credits x 30 hrs = 60 hrs in semester

Course Outcomes:

The students will be able to –

CO1: Perform wastewater analysis by estimating parameters such as COD, BOD, TS, TSS, etc. with additional knowledge about setting up of laboratory scale bioreactors for wastewater treatment.

CO2: Define Potency of the vaccine and Assess quality of toxoid type of vaccine using immunological techniques

CO3: Perform the steps for isolation of Salmonella H and O antigen.

Unit	Unit Title and Contents	Lectures
I	**Practicals based on industrial waste water treatment:** i. Estimation of pollution load of a natural sample (e.g. river water / industrial waste water) ii. Setting up a laboratory experiment to assess degradability of synthetic wastewater	30
II	**Practicals based on industrial production of vaccines** i. Checking the potency of a toxoid based vaccine by immune diffusion assay ii. Preparation of *Salmonella* O and H antigen and estimation withknown antibodies	30

Suggested References 23-MBEP 246: Semester IV

Practicals based on Industrial Waste Water Treatment and Industrial Productionof Vaccines

Choice based Optional Practical Paper (Elective)

Unit	References
I	1. Barthwal R. R. (2002). Environmental Impact Assessment, New Delhi (India). New Age International (P) Limited Publishers. 2. Eaton A. D. (2005). Standard methods for the examination of water and wastewater. American Public Health Association. American Water Works Association. Water Environment Federation. Publisher: Washington, D.C.: APHA-AWWA-WEF. National government publication: English: 21st edition 3. Glasson J., Therivel R. and Chadwick A. (2012). Rutledge-Taylor and Francis Introduction to Environmental Impact Assessment. 4th Edition. 416 pages 4. Srivastava A. K. (2003). Environment Impact Assessment, (A.P.H. Publishing. Corporation, Delhi,ISBN-817648-4423

II	1. Cruickshank R. (1982). Medical Microbiology, 12th Edition, P.403.2. FelixA. (1942) Brit. Med. J. 11: 597. 2. Roitt L. (1994). Essential Immunology. 8th edition. Blackwell Scientific.Oxford, UK.114- 115. 3. Vaerman J. P. (1981). Single radial immune diffusion, in methods in enzymology. 73 (Langone, J. J.And Van Vunakis, H, Eds.) New York. 291- 305.

Semester IV

23-MBET 247: Bioethics, Biosafety, Quality Control and Quality Assurance

Choice based Optional Theory Paper (Elective)

[2 Credits; 30 Lectures]

[1 credit=15 hrs x 60 mins]

Course outcomes:

The students will be able to

CO1: Describe Quality Assurance reviewing and approval of procedures, reviewing records and performing audits.

CO2: Explain Ethical conflicts in microbiological and biotechnological research

CO3: Describe Biosafety Regulatory bodies (Role and functions)

Unit	Unit Title and Contents	Lectures
I	**Bioethics and Biosafety** **A. Bioethics** i. Concept of ethics and bioethics with respect to microbiologicalresearch ii. Principles of bioethics. iii. Ethical conflicts in microbiological and biotechnological research iv. Biological Diversity Act: conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of utilization of genetic resources **B. Biosafety** Regulatory bodies (Role and functions) i. Advisory Committee: Recombinant DNA Advisory Committee (RDAC) **ii**. Regulatory / Approval Committees: a. Genetic Engineering Appraisal Committee (GEAC) b. Review Committee on Genetic Manipulation (RCGM) c. SIRO (DSIR) d. Institutional Biosafety Committee (IBSC): Importance of Biosafety Institutional Biosafety Committees (IBSCs) Laboratory associated infections and hazards Bio safetyregulation: handling of recombinant DNA products and process in industry and in institutions iii. Monitoring Committees: a. State Biotechnology Coordination Committee (SBCC) b. District Level Committee (DLC)	15

II	**Quality Control and Quality Assurance Quality Control:** Assessment of suitability of components and products Evaluation of the performance of the manufacturing process A. Quality Assurance reviewing and approval of procedures, reviewingrecords and performing audits B. Good Manufacturing Practices (GMP) and Good Laboratory Practices(GLP) C. Regulatory bodies (Role and functions): **i.** The Central Drugs Standard Control Organization (CDSCO) **ii.** National Accreditation Board for Testing and Calibration Laboratories (NABL) **iii.** Food Safety and Standards Authority of India (FSSAI): Food and water Laboratories **iv.** International Standard ISO/IEC 17025:2017(E). **v.** Bureau of Indian Standards -IS 14648 (2011): Methods of Testfor Microbiological Examination of Industrial Product **vi.** (examples Cosmetics and Cosmetic Raw Materials) **vii.** The Central Pollution Control Board (CPCB)- Prevention and control of water and air pollution and improvement of the quality of air.	15

Suggested References 23-MBET 247: Semester VI Bioethics, Biosafety, Quality Control and Quality Assurance
Choice based Optional Theory Paper (Elective)

Unit	References
I	1. Biotechnology: A comprehensive treatise (Vol. 12). Legal economic and ethical dimensions VCH. (2nded) ISBN- 10 3527304320. 2. Encyclopedia of Bioethics 5 vol set, (2003) ISBN-10: 0028657748. 2. Thomas J.A. and Fuch R. L. (2002). Biotechnology and safety Assessment (3rd Ed) Academic press. 3. Notification from Department of Biotechnology, Ministry of Science and Technology, India. (2020) Revised simplified procedures/guidelines on Import, Export and Exchange of GE organisms and product thereof for R& D purpose. File no. BT/BS/17/635/2015-PID. dated-17/01/2020 4. https://ibkp.dbtindia.gov.in/ 5. Ministry of Law And Justice (Legislative Department) New Delhi, the 5th February, 2003/Magha 16, 1924 (Saka) published for general information: The Biological Diversity Act, 2002 No. 18 of2003 [5th February, 2003]

II	1. Draft Manual on method of microbiological testing (2016) microbiology of foods. Food safety and Food Standards. https://old.fssai.gov.in/Portals/0/Pdf/Microbiological_Testing_Foods_Draft_Manual_06_09_2016.pdf 2. Eleftheriadou M. and Tsimillis K. C. (Eds), Eurachem guide: Accreditation for Microbiological Laboratories, Second edition (2013), ISBN: 978-91- 87017-92-6. Available from www.eurachem.org. 3. https://archive.fssai.gov.in/home/food-testing/food-testing- manual.html. 4. https://cdsco.gov.in/opencms/opencms/en/About-us/Functions/ 5. https://cdsco.gov.in/opencms/opencms/en/Home/ 6. https://cpcb.nic.in/functions/ 7. https://www.iso.org/obp 8. International Standard ISO/IEC 17025:2017(E). General requirements for the competence of testing and calibration Laboratories. Third edition. 2017-11 9. IS 14648 (2011): Methods of Test for Microbiological Examination of Cosmetics and Cosmetic Raw Materials. https://law.resource.org/pub/in/bis/S11/is.14648.2011.pdf 10. Manual for Good Food Laboratory Practices (GFLPs). 2018. Food Safety and standards Authority of India (FSSAI) Ministry of Health and Family Welfare Government of India, New Delhi 04. Issue Date -11-Feb-2019 11. Manual of Methods for Analysis of Water 2016. Food Safety and Standards Authority of India (FSSAI), Ministry of Health and Family Welfare Government of India, New Delhi 12. National Accreditation Board for Testing and Calibration Laboratories(NABL). (2019) Specific Criteria for Accreditation. NABL 112. IssueNo:04. Issue date- 11-Feb-2019

23-MBEP 247: Semester IV

Practicals based on Bioethics, Biosafety, Quality Control and Quality Assurance Choice based Optional Practical Paper (Elective)

(Total Workload): - 2 credits x 30 hrs = 60 hrs in semester

Course outcomes:

The students will be able to

CO1: Apply NABL norms for Calibration of instruments

CO2: Perform tests for drinking water as per Food Safety and Standards Authority of India (FSSAI) regulations.

CO3: Analyze Water/butter/cheese/milk products and report if they satisfy FSSAI guidelines.

Unit	Description	Lectures
I	**A. NABL norms for Calibration of:** i. Autoclave- Calibration of pressure gauge and temperature by thermal mapping, sterility testing, SOP preparation. ii. Laminar Air Flow- checking the functioning of UV light by colony count method and sterility checking by blood agar media plate method, SOP preparation.	15
	B. Food Safety and Standards Authority of India (FSSAI) Regulations Test Methods for Drinking Water i. Detection of sulphite-reducing anaerobes (Clostridia) ii. Detection of bacteriophage and titre determination.	15
II	**A. Food Safety and Standards Authority of India (FSSAI) Regulations Test Methods for Water/butter/cheese/milk product for Processed Food Industry:** (perform any two) i. Proteolytic Plate Count ii. Lipolytic Plate Count iii. Thermophillic Bacterial Count (for Dairy Industry-Processing) iv. Slime Forming Bacteria (for Dairy industry-Hot water	15
	B. Food Safety and Standards Authority of India (FSSAI)Regulations for Microbiological Testing of food: i. Fermentation Test (Incubation test for Cans, Tetrapacks, Standypouches). ii. To study food (FSSAI) Regulations for Microbiological Testing of food through industrial visit and writing of report on it.	15

Suggested References 23-MBEP-247: Semester IV Practical based on bioethics, biosafety quality control and quality assurance Choice based Optional Practical Paper (Elective)	
Unit	**References**
I	**A. NABL norms for Calibration of** National Accreditation Board for Testing and Calibration Laboratories (NABL). (2019) Specific Criteria for Accreditation. NABL 112. Issue No: 04 Issue Date:11-Feb-2019
	B. Food Safety and Standards Authority of India (FSSAI) Regulations Test Methods for Drinking Water Manual of Methods for Analysis of Water 2016. Food Safety and Standards Authority of India (FSSAI), Ministry Of Health and Family Welfare Government of India, New Delhi
II	**A. Food Safety and Standards Authority of India (FSSAI) Regulations Test Methods for Water/butter/cheese/milk product for Processed Food Industry:** Manual of Methods for Analysis of Water 2016. Food Safety and Standards Authority of India (FSSAI), Ministry Of Health and Family Welfare Government of India, New Delhi
	B. Food Safety and Standards Authority of India (FSSAI)Regulations for Microbiological Testing of food: 1. Draft manual on method of microbiological testing (2016) microbiology offoods. Food safety and Food Standards. Available at:https://old.fssai.gov.in/Portals/0/Pdf/Microbiological_Testing_Foods_Draft_Manual_06_09_2016.pdf 2. https://archive.fssai.gov.in/home/food-testing/food-testing-manual.html. 3. Manual for Good Food Laboratory Practices (GFLPs). 2018. Food Safety and Standards Authority of India (FSSAI), Ministry Of Health and Family Welfare Government of India, New Delhi

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