2.2 PHARMACEUTICAL MICROBIOLOGY AND BIOTECHNOLOGY (THEORY) 75 hours; 3 hours/week

- Introduction, a brief history of microbiology (spontaneous generation, theory of biogenesis, germ theory of disease, contributions of Antony Van Leeuwenhoek, Edward Jenner, Robert Koch, Louis Pasteur and Alexander Fleming), pharmaceutical importance of microorganisms.
 4 hours; 2-5 marks
- 2. Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, culture media with emphasis on special purpose media, growth curve, continuous growth, synchronous growth, isolation and preservation [space] methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count), identification of bacteria using colony characters, staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).
- Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus.
 4 hours; 2-5 marks
- 4. Study of principle, procedure, merits, demerits and applications of thermal, radiation, gaseous (ethylene oxide), filtration methods of sterilization. Brief study on sterilization indicators. Study of general methods of sterility testing including interpretation of its results.

 12 hours; 10-15 marks
- Ideal properties, classification and factors affecting the action of disinfectants. Mode of action and uses of phenols, halogens, metallic salts and aldehydes. Evaluation of bacteriostatic, bactericidal (phenol coefficient methods) properties of disinfectants and preservatives.
 8 hours; 5-9 marks
- 6. Types of immunity, antigens and antigenic determinants, structure and formation of antibodies, classification of immunoglobulins, antigen-antibody reactions (precipitation and agglutination reactions), Types of vaccines, difference between vaccine & sera, killed vaccine & attenuated vaccine, preparation of BCG vaccine, Tetanus toxoid and Polio vaccine, immunization program and importance of booster dose, diagnostic tests viz. ELISA, Western blot, Widal and Mantoux.

12 hours: 12-17 marks

7. Introduction to fermentation technology, design and operation of a fermenter, production of streptomycin and vitamin B_{12} . Principles and methods of microbiological assays with reference to streptomycin and vitamin B_{12} .

8 hours; 7-10 marks

8. Introduction to recombinant DNA technology, tools and techniques of gene manipulation, production of recombinant insulin and hepatitis B vaccine.

5 hours; 5-7 marks

9. Types of cell lines, basic requirements, advantages, disadvantages and applications of animal cell culture. Production and applications of monoclonal antibodies.

5 hours; 5-7 marks

10. Study of causative organism, mode of transmission, signs and symptoms, treatment and prevention of microbial diseases like cholera, typhoid, tuberculosis, AIDS, malaria and dengue.

5 hours; 5-7 marks

PHARMACEUTICAL MICROBIOLOGY AND BIOTECHNOLOGY (PRACTICALS)

75 hours; 3 hours/week

- 1. Study of apparatus used in experimental microbiology.
- 2. Sterilisation of glassware, preparation and sterilisation of media.
- 3. Staining techniques Simple staining*, Gram's staining. **
- 4. Motility testing*
- 5. Total and viable count*.
- 6. Isolation and maintenance of pure culture*.
- 1. Sensitivity testing.*
- 2. Microbiological assay of antibiotics by cup plate method**.
- 3. Sterility testing by direct transfer and membrane filtration technique*.
- 4. Initiation of callus culture*
- 5. Estimation of DNA by spectroscopic method.**
- 6. Estimation of RNA on spectroscopic method. **

SCHEME OF EXAMINATION

Total	- 70 Marks
5. Viva-Voce	-10 Marks
4. Minor experiment*	-10 Marks
3. Minor experiment*	-15 Marks
2. Major experiment**	-25 Marks
1. Synopsis	-10 Marks

PHARMACEUTICAL MICROBIOLOGY REFERENCE BOOKS

- 1. *Hugo and Russell's* Pharmaceutical Microbiology (2004), 7th Ed, Blackwell Publishing Ltd, 9600 Garsington Road, Oxford OX4 2DQ, UK
- 2. Microbiology: an introduction (2010) by Gerard J. Tortora, Berdell R. Funke, Christine L. Case, 10th ed., Pearson Education, Inc., San Francisco, CA 94111
- 3. Prescott, Harley and Klein's Microbiology 2 Ed, W. C Brown Publishers, 1993.
- 4. Pelczar Reid, Microbiology, 5th Ed, Tata MC Graw-Hill Publishers company, 1993.
- 5. Ananthnarayan and Pannicker, Text Book of Microbiology, 6 Ed, Orient-longman, Chennai, 1995.
- 6. S.P. Vyas and Dixit Pharmaceutical Biotechnology, 1 Ed, CBS Publishers & distributors, NewDelhi, 1998.
- 7. S.S Kori Pharmaceutical Biotechnology, .Fundamentals and Applications, 1 Ed Vallabh Prakashan, New Delhi.
- 8. Microbiology: A Laboratory Manual By Cappuccino, Pearson Education India, 2005
- 9. Frobisher M, Fundamentals of Microbiology,9 Ed, Toppan Company Ltd. Tokyo. Japan.
- 10. Collins C.H. Microbiological Methods. 6 Ed, Butterworth, London. 1989.
- 11. Stanier, Ingraham, General Microbiology 5 Ed., Wheelies and Painter. 1987.
- 12. Cooper & Gunn's Tutorial Pharmacy, 9 Ed, CBS Publisher and Distribution, 1986.
- 13. Roitt, Immunology, 4 Ed, Harwood academic publishers, Mosby, London.1997.
- 14. Bentley's Text Book of Pharmaceutics by Rawlins 8 Ed, ELBS publication, 1984.
- 15. Pharmacopoeia of India Govt. of India

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Autoclave	02 nos
2. Hot air oven	01 no
3. B.O.D. Incubator	01 no
4. Refrigerator	01 no
5. Laminar air flow	01 no
6. Colony counter	02 nos
7. Zone reader	01 no
8. Spectrophotometer	01 no
9. Microscope with stage	20 nos
10. Sterility testing unit	01 no