A Skill Development Course

Contents of

‘Pharmaceutical Techniques’

(Academic Year 2018-19)

Department of Microbiology

Modern College of Arts, Science and Commerce
Shivajinagar, Pune 411005

Course Contents

Theory

1. **Pharmaceutical Industry-Structure-History**
2. **Introduction to Practices in Pharmaceutical Industry**
   a. cGMP (Current Good Manufacturing Practices)
   b. cGLP (Current Good Laboratory Practices)
   c. cGMP (Current Good Marketing Practices)
   d. cGCP (Current Good Clinical Practices)
3. **Setting up Laboratory with reference to Microbiology aspects**
   a. Principles of SOPs (location, equipment, plan of premises, accreditations, HR Qualifications etc.)
   b. Feasibility Report Preparation
4. **Quality Assurance (QA)**
   a. Qualifications and Analytical validations of area, equipment, testing methods, etc.
   b. Process simulation activity / Media fill activity
   c. Sterility assurance and validation
   d. Introduction to disinfectants, fumigants, sterilants and their validations.
5. **Quality Control (QC)**
   a. SOPs (Standard Operating Procedures) and STPs (Standard Testing Procedures)
   b. Document preparation and documentation control
   c. Sampling methods
   d. Product stability studies from microbiological aspects
6. **Methods in Pharmaceutical Microbiology**
   a. Environmental monitoring
   b. Biocompatibility test
   c. Microbial Limit test
   d. Sterility test
   e. LAL test
   f. Water analysis

7. **Biotechnology products**
   a. Vaccine development and manufacturing
   b. Sterilization techniques with reference to QA and QC
   c. Cell culture techniques

8. **Qualifications and validations in pharmaceutical industry**
   a. Validation of water system
   b. Validation of environment
   c. Qualification and validation of sterilization processes

9. **Role and responsibilities of microbiologist in pharmaceutical industry**

10. **Research and development aspects of Pharmaceutical industry**

11. **Regulatory Affairs (RA)**
    a. ICH and WHO guidelines
    b. Drug rules followed by Pharmaceutical industries (USFDA, MHRA [UK] and ISO)
    c. Domestic and International

Practical (Demonstration)

1. **Sterility testing**
2. **Microbial Limit Test [MLT]**
3. **Bacterial endotoxin testing [BET]**
4. **Designing SOPs related to Microbiology**
5. **Industrial visit: Pharmaceutical Institute / Industry**