Rayat Shikshan Sanstha's

Yashavantrao Chavan Institute of Science, Satara (Autonomous)

Diploma course

MICROBIAL QUALITY CONTROL IN INDUSTRIES

DEPARTMENT OF MICROBIOLOGY

Year: 2020-21

Objectives:-

Education that a student has acquired in his graduate studies is not enough to meet the demands when he/she is working in a responsible position in a pharmaceutical or in microbial industry. In most of the organizations fresher candidate are not given the job oriented instruction that they need and they find it difficult to adapt themselves to the working situations in which they are called upon to operate.

The diploma course in Microbial quality control in industries offered by the Microbiology Department has specially designed to cater the requirements of such students.

- The course aims at covering the basic techniques and their applications to pharmaceutical industries.
- Students should get basic knowledge about antimicrobial agent and about efficacy testing.
- Students should also understand tools and techniques used in antimicrobial testing.
- Students should also understand regulations and recommendations about pharmacopeia.

Goals:-

The specific goal of the Advance diploma course are:

- To prepare graduate students (B.Sc.) with in depth knowledge and skill for professional careers in microbiology.
- To provide consultancy services to society.

- Provide an environment which fosters the continuous improvement and innovations in the Subject.
- Inculcate among the students skills and value of dignity of labor.

Unit I- Microbiological standards in Pharmaceutical industries 12

A) Design of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

B) Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

C) Assessment of a new antibiotic and testing of antimicrobial activity of a new substance. General aspects-environmental cleanliness.

Unit II- Quality control and Assurance (SOP, GLP, GMP) 12

A) GMP and regulations

1. Introduction
2. Good manufacturing practice
3. Importance of medicines in public health
4. The role and development of pharmacopoeias
5. Importance of inspections in the lifecycle of medicines
6. Role of the company regulatory affairs department
7. Documentation
8. Conclusion

B) Cleaning and disinfection

1. Introduction
2. Cleaning
3. Disinfection
4. Good manufacturing Practice requirements
5. Measuring disinfection effectiveness: environmental monitoring
6. Disinfectant efficacy
7. Conclusion

Unit III- Testing of pharmaceutical products **12**

Microbiology laboratory techniques

1. Introduction
2. Good laboratory practice and laboratory safety
3. Aseptic technique
4. Cultures and identifications
5. Microscopy
6. Pharmacopeia and microbiological tests
7. Microbiological examination of nonsterile products
8. Measurement of cell concentration in suspension by optical density
9. Sterility testing
10. In vitro and in vivo testing for pyrogens and endotoxins
11. Microbiological assay of antibiotics
12. Environmental monitoring
13. Water analysis
14. Conclusion

Unit IV- Bio burden determination **12**

1. Microbial count
2. Units of measurement
3. No sterile products and microbial limits testing
4. In-process material bio burden assessment
5. Presterilization bio burden assessment
6. Alternative methods of bio burden assessment

Books recommended for theory-

1. Handbook of microbiology quality control- Norman A Hodges and Stephen P. Denyer.
2. Pharmaceutical microbiology- 6th edition- W.B. Hugo and A.D. Russell
3. Basic experimental microbiology by Ronald M. atlas, Alfred E. Brown
4. The basic pharmacology by – Harper
5. Biochemistry of antimicrobial action – Chapman and Hall, London.
6. Microbial quality assurance in pharmaceuticals by - Sally F. Bloomfield
7. Pharmaceutical quality control Microbiology- A guide Book to the basics, Scott Sutton
8. Pharmaceutical microbiology by- Purohit

9. Industrial, Pharmaceutical microbiology- I, Standard and control editors- Doctor N. Hodge

Practical Course **96**

List of Practicals

1)Microbiological analysis of Air
2) Microbiological analysis of equipments & personnel.
3) Microbiological analysis of Raw materials & finished products.
4) Microbiological analysis of spoiled pharmaceutical products- SPC
5) Microbiological analysis of water- MPN
6) Presumptive test of water
7) Confirm test of water
8) Completed test of water
9) Extraction of bioactive ingredients from plant and its activity fraction
10) Determination of MIC of drug
11) Estimation of antimicrobial activity using CLSI
12) Determination of microbial load of non-sterile products- Ointment, capsule
13) Good laboratory practices (GLP)
14) Good manufacturing practices (GMP)
15) Quality Assurance- Definition, Rules and Regulations
16) Susceptibility testing of antibacterial agent
17) Susceptibility testing of antifungal agent
18) Susceptibility testing of antiprotozoal agent
19) Kirby-Bauer Method- Paper disc diffusion method
20) Agar dilution technique
21) Diffusion method by E Test
22) Diffusion method by Stoke method
23) Diffusion method by Gradient plate technique.
24) Determination of Phenol Coefficient ratio

Learning Outcomes-

After performing the practical course students will be able to –
1. Evaluate the microbiological analysis of environment in industries.
2. Comprehend the concept of SOP, GMP, GLP in industries.
3. Practically perform antimicrobial testing.

Suggested books for practicals-

1. Introduction to practical biochemistry by- D. Plummer,J Willey and Sons.
2. Introduction to microbial technique by Gunasekaran.
3. Experimental microbiology by Patel and Patel.
4. Biochemistry of antimicrobial action, Chapman and Hall London,
Franklin T.J. and Snow G A. 1975
5. Goldsmith A. Aronow L. Kalman S.M. (1969) the basic pharmacology, Harper international edition, New York
6. Kokate C K, Purohit A P, gokhale A B (2000), Pharmacology 4th edition, Nirali prakashan

Project **24**

Student will have to undertake one project as a part of the course