

**Rayat Shikshan Sanstha's
Yashwantrao Chavan Institute of Science, Satara
Department of Microbiology & Biochemistry**

B.Sc. II Diploma Course.

Microbial Quality Control And Assurance

Objectives :-

- a) Students should be able to
- b) Collect and preserve the samples from different areas of pharmaceutical industries, count the microbial level in the same sample.
- c) Detect and isolate specific microorganism from the sample by enrichment method.
- d) Perform the endotoxin testing of sample and lysate and also able to perform microbiological assay of penicillin.
- e) Perform sterility testing of different components in industries.
- f) Prepare stock reagent, molar and normal solutions.

DMiT 301 Microbiology in pharmaceuticals, food, dairy industry

Unit – I :- Quantitative Microbial Enumeration in products .

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- g) Sample preparation- Water-Soluble Products (Aqueous), Non-fatty Products Insoluble in Water, Fatty Products, Fluids or Solids in Aerosol Form, Transdermal Patches, medical device, gases, neutralization/removal of antimicrobial activity.
- h) Counting methods – pour plating, membrane filtration, spread plating, Miles & Misra plating, MPN.
- i) Turbidometric methods.
- j) Method validation.

Unit – II :-Pharmacopoeial methods for detection of specified microorganisms.

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- a) Introduction & scope.
- b) Significance & applicability of microbial limit test.
- c) General principles used to conduct of tests for specified organisms.
- d) Bile-Tolerant Gram-Negative Bacteria
- e) Detection of *Staphylococcus aureus*.
- f) Detection of *Pseudomonas aeruginosa*.
- g) Detection of *E. coli* & *Enterobacteriaceae*.

- h) Detection of *Salmonella* sp.
- i) Detection of *Clostridia*.
- j) *Candida albicans*

Unit- III:- Endotoxin testing.

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- a. Introduction – regulatory development.
- b. Introduction to LAL test- Gel clot method- Principle & procedure.
- c. Gel clot lysate sensitivity test.
- d. Product interference.
- e. Evaluation of antibiotic- Penicillin
- f. Microbiological assay- chemical Assay.
- g. Liquid disinfectant – suspension test, phenol coefficient test & dilution test.

Unit- IV:- A) Sterility Testing.

- a. Culture media and incubation
- b. Importance
- c. Precautions against microbial contamination
- d. Culture media and incubation temperature
- e. Growth promotion test of aerobes, $\pm 2.5^\circ$. Anaerobes, and fungi
- f. Diluting and rinsing fluids , method suitability test
- g. Test for sterility of the product- number of sample and procedure, direct inoculation, , interpretation filtration

B) Preparation of stock reagent, Media, Cultures & chemicals.

- h. Solutes, solvents & solutions.
- i. Percentage solution – w/v & v/v.
- j. Normal solution.
- k. Molar & milimolar solutions.
- l. Standard solutions, stock solutions & working solutions.
- m. Buffer solutions
- n. Preparation and Sterilization of microbiological Media
- o. Preparation of Standard cultures and growth Promotion Testing of sterilized of Microbiological Media

References:

1. Handbook of Microbiological Quality Control (Pharmaceutical & Medical Devices)
Edited by Rosamund M. Baird , Norman A. Hodges.,Stephen P. denyer.

2. Rober E. Boyd , General Microbiology- 2nd Edition. Times MIRROR / Moshi college, Publicing Verginia.
3. Brock T.D. Madgium M.T. Biology of Microorganisms . Pentice Hall of India PVT.Ltd.
4. Pharmaceutrical Quality control Microbiology : A Guide book to the Basics. Scott Sutton
5. Industrial Pharmaceutical Microbiology - I, Standard & Controls Editors –Doctor Norman Hodges & Prof. Geoff Hanlon University of Brighton.
6. Industrial Pharmaceutical Microbiology - II , Standard & Controls Editors –Doctor Norman Hodges & Prof. Geoff Hanlon University of Brighton.
7. Pharmecutical Microbiology by Purohit.
8. Handbook of microbiological quality control – NA Hoges, S P Denyer, R M Baird 2003
9. Pharmaceutcal Microbiology : Essentials of Quality Assurance & Quality control. Tim Sandle
10. Microbial Quality Assurance in Pharmaceutcals, cosmetics & Toiletries :- by Sally F. Bloomfield.

Practical

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1. Measurement of bacterial growth of E.coli by turbidometric method.
2. Measurement of micro-organisms in water by membrane filters technique.
3. Detection of *Staphylococcus aureus* in media component.
4. Detection of Pseudomonas in final drug.
5. Detection of E-Coli in water sample.
6. Detection of Salmonella in final produced.
7. MLT method suitability test.
8. Microbial enumeration of total aerobic count.
9. Enumeration of total combined yeast & mold count.
10. Principle & working of centrifuge colorimeter, UV, Visible Spectrophotometer
11. Preparation of standard solution – normal saline.
12. Preparation of 1 N HCL, 1N NaOH
13. Preparation of 1 Molar glucose , NaOH
14. Preparation of Phosphate buffer of any PH
15. Preservation of culture by sub culturing.
16. Preservation of culture by oil overlay method.
17. Determine the purity of preserved culture.
18. Microbiological assay of penicillin.
19. Chemical assay of Penicillin.
20. Determine the phenol coefficient of dettol by Radial Walkar method.
21. Determine suspension test of Lysol.
22. Perform agar dilution method of streptomycine .
23. Demonstration of LAL test.
24. Validation of autoclave.
25. Validation of hot air oven.

Learning outcome:-

After performing the practical course, student will be able to:

1. Analyze microbial load of samples from pharmaceutical industries.
2. Evaluate sterility of pharmaceutical products.
3. Determine endotoxin levels in samples.
4. Prepare different types of stock reagents and molar and normal solutions.

References :-

1. Keith Wilson & John Walker – 1994. Practical Biochemistry, Principles & Techniques.
2. Principles of applied biomedical instrumentations- A. Geddes & LE Baken John Wiley & Sons.
3. Instrumental methods of analysis – Den Williard & Merrit- Asian edition.
4. Manual of Diagnostic Microbiology- Dr.B.J. Wadhar & Dr.G.L. Bhoosreddy - 1st Edition Himalaya Publishing House.
5. Basic experimental Microbiology by Ronal M. Atlas, Alfred E. Brown, Kenneth W.Dobra, Wonas Miller (1986) Pren- Tice Hall.
6. Biologics guide to principles, techniques of practical Biochemistry by K.Wilson and K.H. Goulding Edward Arnold Publications.

Project

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