

**Department of Microbiology**

**Revised Syllabus of II Year Diploma Program (UG)**

**Title of Program: Microbial Quality Control**

**Syllabus Structure (UG)**

Year	Semester	Course No.	Course Code	Contact Hours	Credits (1Credit=15 H)	Total Marks	
2	III	CT III	DMIT 303	30	2	75	
		CL III	DMIL303	60	2	75	
	IV	CT IV	DMIT 404	30	2	75	
		CL IV	DMIL404	60	2	75	
	Annual	CP II	DMIP202	30	1	50	
	Industrial and or Incubation and or Research and or Field Training				30	1	-
	<b>Total</b>				<b>240</b>	<b>10</b>	<b>350</b>

C: Course, T: Theory, L: Laboratory (Practical), P: Project

Total No. of Courses: 6 (Theory: 02, Practical: 02, Project: 01)

Theory and Practical: Semester, Project: Annual

**Semester III**

**CT-III: DMiT 303**

**Title: Microbiology in Pharmaceuticals, Food and Dairy industry-I  
(Contact Hours: 30 Credits: 2)**

**Learning Objectives:**

**Students should be able to -**

- 1) Collect and preserve the samples from different areas of pharmaceutical industries, count the microbial level in the same sample.
- 2) Detect and isolate specific microorganism from the sample by enrichment method.
- 3) Learn about biosafety cabinets.
- 4) Learn Molecular methods to determine microbes in samples

**Unit I: Quantitative Microbial Enumeration in products. (15)**

- a) 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.
- b) Counting methods – pour plating, membrane filtration, spread plating, Miles & Misra plating, MPN.
- c) Turbidimetric methods.
- d) Method validation.
- e) Biosafety cabinets – Working of biosafety cabinets, using protective clothing, specification for BSL- 1, BSL-2, BSL-3. Discarding biohazardous waste.

**Unit II: Pharmacopeial methods for detection of specified microorganisms (15)**

- 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) Enrichment and Detection of specific microorganisms – *E. coli*, *Staphylococcus aureus*, *Pseudomonas sp.*, *Salmonella sp.*
- f) Introduction to Molecular methods to determine microbes in samples- Nucleic acid probes, PCR based detection, biosensors.

**Learning Outcomes:**

After completion of the unit, Student will able to:

- 1) Collect and preserve the samples from different areas of pharmaceutical industries, count the microbial level in the same sample.
- 2) Develop a very good understanding of practical aspects of microbiological safety and various detection methodologies
- 3) Use of different microbiological media in food and pharmaceutical industries.
- 4) Learn molecular methods to determine microbes in samples

**Reference Books:**

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. Pharmaceutical 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. Pharmaceutical Microbiology by Purohit.
8. Handbook of microbiological quality control – NA Hoges, S P Denyer, R M Baird 2003
9. Pharmaceutical Microbiology: Essentials of Quality Assurance & Quality control. Tim  
Sandle
10. Microbial Quality Assurance in Pharmaceuticals, cosmetics & Toiletries :- by Sally F.  
Bloomfield

**CL-III: DMIL 303: Practical**  
**(Contact Hours: 60 Credits: 02)**

**Learning Objectives:**

Students should be able to

- 1) Measure growth of microorganism using various techniques
- 2) Enrich and detect specific microorganism in pharmaceutical component.
- 3) Know about Microbial Limit Test
- 4) Enumerate yeast and detect molds
- 5) Know principle and working of various laboratory instruments

**List of Practicals**

**(15)**

1. Measurement of bacterial growth of *E. coli* by turbidimetric method.
2. Measurement of micro-organisms in water by membrane filters technique.
3. Enrichment of *Staphylococcus aureus*
4. Detection of *Staphylococcus aureus* in media component.
5. Enrichment of *Pseudomonas*
6. Detection of *Pseudomonas* in final drug.
7. Enrichment of *E. coli*
8. Detection of *E. coli* in water sample.
9. Enrichment of *Salmonella*
10. Detection of *Salmonella* in final produced.
11. MLT method suitability test.
12. Microbial enumeration of total aerobic count.
13. Enumeration of yeast
14. Detection of mold
15. Principle & working of centrifuge, colorimeter, UV, Visible Spectrophotometer

**Learning Outcomes:**

After completion of the unit, Student will able to

- 1) Measure growth of microorganism using various techniques
- 2) Enrich and detect specific microorganism in pharmaceutical component.
- 3) Know about Microbial Limit Test
- 4) Enumerate yeast and detect molds
- 5) Know principle and working of various laboratory instruments

### Reference Books:

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 Dignostic 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.

**Semester IV**  
**CT-IV: DMIT 404:**

**Title: Microbiology in Pharmaceuticals, Food and Dairy industry-II**  
**(Contact Hours: 30 Credits: 2)**

**Learning Objectives:**

Students should be able to

- 1) Learn the endotoxin testing of sample and lysate
- 2) Learn microbiological assay of penicillin.
- 3) Learn sterility testing of different components in industries.
- 4) Learn determining microbial quality of milk by various methods.
- 5) HACCP for Food Safety and Microbial Standards.

**Unit I: - A) Endotoxin testing** **(15)**

- 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.

**B) Ascertaining microbial quality of milk** by MBRT, Rapid detection methods of microbiological quality of milk at milk collection centers (COB, 10 min Resazurin assay)

**Unit II: A) Sterility Testing** **(15)**

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

**B) HACCP for Food Safety and Microbial Standards:**

Hazard analysis of critical control point (HACCP) - Principles, flow diagrams, limitations  
Microbial Standards for Different Foods and Water – BIS standards for common foods and drinking water.

### Learning Outcomes:

After completion of the unit, Student will able to

- 1) Learn the endotoxin testing of sample and lysate
- 2) Learn microbiological assay of penicillin.
- 3) Learn sterility testing of different components in industries.
- 4) Learn determining microbial quality of milk by various methods.
- 5) HACCP for Food Safety and Microbial Standards.

### Reference Books:

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,  
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3. Brock T.D. Madgium M.T. Biology of Microorganisms. Pentice Hall of India Pvt.Ltd.
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Hodges & Prof. Geoff Hanlon University of Brighton.
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8. Handbook of microbiological quality control – NA Hoges, S P Denyer, R M Baird 2003
9. Pharmaceutical Microbiology: Essentials of Quality Assurance & Quality control. Tim  
Sandle
10. Microbial Quality Assurance in Pharmaceuticals, cosmetics & Toiletries : by Sally F.  
Bloomfield.
11. Principles of Sensory Evaluation of Food- 1965 MA Amerine, RM, Pangborn and EB  
Roessler, Elsevier.
12. Quality Control in the Food Industry V1, S Herschdoerfer, ISBN: 9780323152068,:  
Academic Press, 1967

**CL-IV: DMIL404: Practicals**  
**(Contact Hours: 60 Credits: 02)**

**Learning Objectives:**

Students should 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. Acquire laboratory skills of testing microbial load in milk.

**List of Practicals**

**(15)**

1. Preservation of culture by sub culturing.
2. Preservation of culture by oil overlay method.
3. Determine the purity of preserved culture.
4. DMC of milk sample
5. MBRT of milk samples and their standard plate count.
6. Alkaline phosphatase test to check the efficiency of pasteurization of milk.
7. Resazurin Assay for checking milk quality
8. SPC of given food sample
9. Microbiological assay of penicillin.
10. Chemical assay of Penicillin.
11. Determine suspension test of Lysol.
12. Perform agar dilution method of streptomycin.
13. Demonstration of LAL test.
14. Validation of autoclave.
15. Validation of hot air oven.

**Learning Outcomes:**

After completion of the unit, Student is able to

1. Analyze microbial load of samples from pharmaceutical industries.
2. Evaluate sterility of pharmaceutical products.
3. Determine endotoxin levels in samples.
4. Acquire laboratory skills of testing microbial load in milk.
5. Acquire laboratory skills of testing microbial load in food sample.

**Reference Books:**

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 Dignostic 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.

**CP-II: DMIP 202: Project  
(Contact Hrs. 60, Credits: 2)**

**Industrial and or Incubation and or Research and or Field Training  
(Contact Hrs. 60, Credits: 2)**

**BOS Sub-Committee**

1. Ms. M.M. Raut -Chairperson
2. Ms. M.S. Shinde- Member

**Expert Committee**

1. Dr. Bharat Ballal  
[Head of Microbiology Department,  
Y.M. College, Pune]
2. Mr. Sanjay Chavan  
[ACG Associated Capsule Pvt. Ltd,  
Shirval]