Karmaveer Bhaurao Patil University, Satara

Syllabus for

Diploma I Microbial Quality Control

Under

Faculty of Science and Technology

(As per NEP 2020)

With effect from Academic Year 2024-2025

Department of Microbiology

Revised Syllabus of Diploma Programme (UG)

Preamble:

This syllabus is framed to give sound knowledge with understanding of Microbial Quality Control and Assurance in Pharmaceutical industries to graduate students at first year of three years of diploma course.The goal of the syllabus is to make setting up an industry related to Microbiology popular, interesting and encouraging to the students. Also this course will help students to be a good employee to various microbiological industries. The new and updated syllabus is based on a basic and applied approach with vigor and depth. At the same time, precaution is taken to make the syllabus as per the needs of industries. The syllabus is prepared after discussion at length with number of faculty members of the subject and experts from industries and alumni working in pharmaceutical, food, dairy industries. The units of the syllabus are well defined, taking into consideration the level and capacity of students.

Program Objectives of the Course:

a) This course guides such students of Microbiology which are willing to work in pharmaceutical and food industries.
b) Even those students which will be placed in various Microbiology, Biotechnology related industries will get benefits from this course.
c) This course not only gives knowledge of industrial processes but also more importantly guides our students about basic essentials of microbial quality control .
d) This course gives theoretical and practical skills needed in industries.

Program Outcomes:

1.Students will be able to understand all the aspects of microbial quality control in microbiological industries.
2.Students will be able to perform various basic techniques in microbiological industries.
3.Students will be able to understand the basics of microbiological industrial process.
4.Students will be able to acquire broad theoretical and practical skills needed in industries.

I Year Diploma Programme

1. Title: Microbial Quality Control
2. Year of Implementation: 2024
3. Duration: One Year
4. Pattern: Semester
5. Medium of Instruction: English
6. Contact hours: 7 hours/week
8. Structure of Course:

Syllabus Structure (UG)

Year	Semester	Course No.	Course Code	Contact Hours	Credits (1Credit=15 H)	Total Marks
1	I	CT I	DMIT 101	30	2	75
		CL I	DMIL101	60	2	75
	II	CT II	DMIT 202	30	2	75
		CL II	DMIL202	60	2	75
	Annual	CP I	DMIP101	30	1	50
			Total	**210**	**9**	**350**
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	-
			Total	**240**	**10**	**350**
	V	CT V	DMIT 505	30	2	75
		CLV	DMIL505	60	2	75
	VI	CT VI	DMIT 606	30	2	75
		CL VI	DMIL606	60	2	75
	Annual	CP III	DMIP303	60	2	100
	Industrial and or Incubation and or Research and or Field Training			30	1	-
			Total	**270**	**11**	**400**
			Total	**720**	**30**	**1100**

D: Diploma, *: Departmental Code (C: Chemistry, MI: Microbiology, CSE: Computer Science (Entire), etc)

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

Total No. of Courses: 10 (Theory: 06, Practical: 06, Project: 03) Theory and Practical: Semester, Project: Annual

Semester I

DMIT 101**: Microbial Diversity and Basic Microbial techniques Part- I**

(Contact Hrs: 30 Credits: 2)

Course Objectives:

Students will be able to

1.Understand microbial diversity and role of microorganisms in pharmaceutical industries.
2. Study microscopy ,classification of stain and Different types of staining procedure.

Unit I: Microbial Diversity **(15)**

A) Branches of Microbiology and Role of microbiology in pharma industry.
B) Study of different types of microorganism with special reference to all related industries
General properties of bacteria.
General properties of viruses.
General properties of fungi.

Unit II: Basic Microbial techniques Part- I **(15)**

A) Microscopy: Types, principle, components and its uses, care and maintenance of compound microscope.

B) Microscopic examination of bacteria.

a) Definitions of stain, dye, mordant, chromogen.

b) Staining techniques – Smear preparation, simple and differential staining (Gram's staining.)

Course Outcomes:

After completion of the unit, Student is able to

1.know the different types of microorganisms related to industries.

2.Understand various basic techniques in microbiological laboratories.

Reference Books:

1. M.J.Jt. , Chan E.C.S. , Krieq, N.R.*Microbiology by Pelczar* 5th Edition, 1986.
2. A.J. Salle, Tata McGraw Hill by *Fundamental principles of bacteriology*.
3. Hindsdill, Crabtree, Good Heart , W.D.Saunders company *Fundamental of Microbiology by Frobisher,* 7th edition.
4. Stanier R,Y. McMilan, London by *General Microbiology* 5th edition.
5. Powar & Daginawala by *General Microbiology Vol. I & II*, Himalaya Publication.
6. Dey & Dey- Allied Agency, Culcutta by *Medical Bacteriology*
7. Ronal M. Atlas , Alfred E. Brown, Kenneth W.Dobra , Wonas Miller by *Basic experimental Microbiology* 1986.

8. K.Wilson and K.H. Biologics guide to *principles, techniques of practical Biochemistry* by Goulding Edward Arnold Publications.
9. Herley and Klein Microbiology by *Prescott*, 2nd Edition.
10. Gunasekaran by *Introduction to Microbial techniques*.

DMIL101: **(Practical):**
(Contact Hrs: 60 Credits: 02)

Course Objectives:

Students will be able to

1.Know and practice the safety measures while working in the Microbiology laboratory and handling of Microscope and instruments.
2.Learn to basic techniques in microbiological laboratory techniques.
3.Stain bacteria by different staining technique
4.Prepare chemical reagents ,staining solution and bacteriological media.

(Minimum 4)

List of Practical's **(15)**

1. General Laboratory regulations
2. Study of parts and functions of compound microscope.
3. Study of laboratory instruments A) Incubator, Hot air oven , Autoclave
4. Study of laboratory instruments B) Colony counter, pH meter, Centrifuge,
5. Study of laboratory instruments C) Colorimeter, distillation unit , Laminar air flow
6. Preparation of cotton plug, wrapping of pipettes and petriplates and their sterilization by using hot air oven.
7. Use of wire loop and pipette and cleaning of petriplates, pipettes and test tubes.
8. Preparation of standard solution-Normal saline, 1N HCL, 1N NaOH, Alcohol.
9. Preparation of safranin and 10% Nigrosin stain.
10. Preparation of peptone water and nutrient broth and their sterilization by autoclaving.
11. Preparation of bacterial suspensions and smear preparation.
12. Morphological study of bacteria by negative staining.
13. Morphological study of bacteria by monochrome staining.
14. Study of Gram nature of bacteria.
15. Demonstration of bacterial motility

Course Outcomes:

After completion of the unit, Student is able to

1.Know and practice the safety measures while working in the Microbiology laboratory.

2.Handle Microscope and laboratory instruments.

3. Gain basic microbiology skills required in industries.

4. Perform staining techniques .

Reference Books:

1.Morella- Mizer- Granato: Laboratory Manual and workbook in Microbiology

2. Sherman Natalie- Microbiology A laboratory Manual 7 th edition –Pearson

3. Prescott M. Lansing- Harley P. John, Kelin A. Donald Laboratory exercise in Microbiology 5 th edition , McGraw –Hill College division

Semester II

DMIT 202 : Basic Microbial techniques Part-II
(Contact Hrs: 30 Credits: 2)

Course Objectives:

Students will be able to

1. Understand the concept of Sterilization, disinfection and sanitization and ensure cleanliness in working area.

2.Know the different techniques of isolation of pure cultures and identification of microorganisms.

Unit I: Basics Concept of QC and QA **15**

A) Aseptic Operation and Containment. Freeze-drying of bio hazardous products.

B) Quality assurance and Quality control in industry-basic principles involved. Good manufacturing practices and Hazard analysis Critical control points in foods, Cosmetic and Pharmaceuticals.

Unit II: Pure culture technique and identification of bacteria. **15**

A) Pure culture technique

a) Definition of pure culture.
b) Methods of isolation of pure culture of bacteria – serial dilution technique, Streak plate technique, spread plate technique and pour plate technique.
c) Methods of isolation of pure culture of fungi.

B) Identification of pure culture of bacteria.

a) Cultural characteristics.
b) Morphological characteristics.
c) Biochemical.
d) Serological.

Course Outcomes:

After completion of the unit, student is able to

1. Study the mode of action, application and advantages of Chemical and physical sterilizing agents.

2. Learn the different methods for isolation and identification of microorganisms.

Reference Books:

1. MA potdar,Nirali prakashan by Pharmaceutical Quality assurance, ,Pune.
2. J.M.Juupron by Juran's quality control handbook, good design practice for GMP pharmaceutical facilities. Andrew A signature,Marcel Dekker, 4th edition.
3. Gunasekaran by Introduction to Microbial techniques.
4. Nelson & Cox by Principles of Biochemistry (Lehninger) 5th Edition.
5. Norman A Hodges and Stephen P. Denyer -Hand Book of Microbiology Quality Control.
6. W.B. Hugo and A.D. Russell by Pharmaceutical Microbiology 6th Edition,.
7. Dr.H.A. Modi by Fermentation technology - Vol. II

DMI L202: **(Practical):**
(Contact Hrs: 60 Credits: 02)

Course Objectives:

Students will be able to

1. Understand the construction ,working and application of laboratory equipments.
2. Determine the efficacy of disinfectant
3. Perform aseptic transfer technique
4. Isolate and identify microorganisms

List of Practical's (15)

1. Preparation and use of disinfectant.
2. Determination of efficacy of Autoclave
3. Determination of efficacy of disinfectants.
4. Checking of efficiency of chemical disinfectant: Phenol coefficient by Rideal -Walker method
5. Sterilization of solutions of sugar, amino acid by membrane filtration
6. Aseptic transfer technique
7. Serial dilution of given sample.
8. Study of streak plate technique.
9. Study of pour plate technique.
10. Study of spread plate technique.
11. Isolation and identification of bacteria from soil (colony and cultural characteristics)
12. Isolation of fungi from given sample.
13. Isolation of yeast from given sample and is microscopic observation.
14. Microscopic observation of fungi.
15. Detection of bacterial endospores.

Course Outcomes:

After completion of the unit, Student is able to

1.Observe microorganisms under microscope.

2.Determine efficacy of disinfectant

3.Learn to critically observe and record the observations of all experiments.

4.Isolate and identify microorganisms.

Reference Books:

1.Morella- Mizer- Granato: Laboratory Manual and workbook in Microbiology.

2. Sherman Natalie- Microbiology A laboratory Manual 7 th edition –Pearson.

3. Prescott M. Lansing- Harley P. John, Kelin A. Donald Laboratory exercise in Microbiology, McGraw –Hill College division ,5 th edition.

DMIP101 (Project):
(Contact Hrs. 30/60, Credits: 1/2)

BOS Sub-Committee
1.Ms..S.S.Shinde , Chairman
2. Ms.S.S.Desai, Member

Expert Committee
1. Mr.Ashok Salunkhe,Academic Expert