Department: Microbiology

Revised Syllabus of III Year Diploma Program (Part Time) (UG)

1. Title of Program:Diploma in Microbiological Quality Control in Industry
2. Year of Implementation: 2022-2023
3. Duration:One Year
4. Pattern:Semester
5. Medium of Instruction: English
6. Contact hours: 7 hours/week
7. 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**
3	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**

Total No. of Courses: 15 (Theory:6, Practical:6, Project:3)

Theory and Practical: Semester, Project: Annual

CT: Course Theory, CL: Course Lab, CP: Course Project, D: Diploma, * : First Letter Name of Subject/Department

Semester V

CT V: DMIT 505: Microbiological quality control in pharmaceutical industry I
(Contact Hrs: 30 Credits: 2)

Learning Objectives: Students will be able to

1. Study the concept of aseptic area, sources of Contamination in aseptic area and methods to prevent contamination
2. Study importance of GMP and regulations and Role of the company regulatory affairs department

Unit I: Unit I- Microbiological standards in pharmaceutical industries 15

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) 15

A) GMP and regulations: Introduction, Good manufacturing practice, Importance of medicines in public health, The role and development of pharmacopoeias, Importance of inspections in the lifecycle of medicines, Role of the company regulatory affairs department, Documentation

B) Cleaning and disinfection: Introduction, Cleaning, Disinfection, Good manufacturing practice requirements, Measuring disinfection effectiveness- environmental monitoring, Disinfectant efficacy

Learning Outcomes: After completion of units**,** student should able to

1. Understand the concept of aseptic area, sources of Contamination in aseptic area and methods to prevent contamination
2. Explain importance of GMP and regulations and Role of the company regulatory affairs department

References :

1. Handbook of microbiology quality control, Norman A Hodges and Stephen P. Denyer. 8th edition, 2019
2. Pharmaceutical microbiology, W.B. Hugo and A.D. Russell, 7th edition , 2009

3. Basic experimental microbiology , Ronald M. atlas, Alfred E. Brown, Macmillan,1986
4. Harper's handbook of Therapeutic pharmacology, R.Marilyn Schmidt, Solomon Margolin,Harper and Row ,1981
5. Biochemistry of antimicrobial action, T. J. Franklin and G.A. Snow, Chapman and Hall, London, 2nd edition, 1971.
6. Microbial quality assurance in pharmaceuticals, Cosmetics and Toiletries,R.Baird and Sally F. Bloomfield, CRC press, 2nd edition, 1996
7. Pharmaceutical quality control Microbiology- A guide Book to the basics, Scott Sutton,Pda publication,1st edition,2007
8. Pharmaceutical microbiology,Saluja A.K., Purohit S.S., Kalkrani H.N.,Agrobios publication.
9. Industrial, Pharmaceutical microbiology, I Standard and control editors- Doctor N. Hodge
10. Pharmaceutical Microbiology, Essentials for quality control and quality assurance, Tim Sandle, Wood head publishing, Elsevier, 2016

CLV: DMIL505: **Practical**
(Contact Hrs: 60 Credits: 02)

Learning Objectives: Students will be able to

1. Study antimicrobial activity using CLSI
2. Study about GMP and GLP
3. Study different diffusion method
4. Study susceptibility testing of antimicrobial agents

List of Practical's (15)

1.Estimation of antimicrobial activity using CLSI
2. Study of Good laboratory practices (GLP)
3. Study of Good manufacturing practices (GMP)
4. Study of Quality Assurance- Rules and Regulations
5. Study of Paper disc diffusion method using Kirby-Bauer Method
6.Determination of MIC by Agar dilution technique
7. Determination of antimicrobial sensitivity by E Test
8. Determination of antimicrobial sensitivity by Stoke method
9. Determination of antimicrobial sensitivity by Gradient plate technique.
10. Susceptibility testing of antibacterial agent
11. Susceptibility testing of antifungal agent
12. Susceptibility testing of antiprotozoal agent
13. Determination of MIC of drug
14.Determination of Phenol Coefficient ratio
15.Extraction of bioactive ingredients from plant and its activity fraction

Learning Outcomes: After completion of practicals, student should able to

1. Understand estimation of antimicrobial activity using CLSI
2. Understand about GMP and GLP
3. Use different diffusion method
4. Understand susceptibility testing of antimicrobial agents

References:

1. Introduction to practical biochemistry , David T. Plummer, McGraw-Hill Book Company (U.K) Ltd., London, Volume 6, 1978.
2.Laboratory Manual in Microbiology, P .Gunasekaran, New age International(P) Ltd, First Edition,1995.
3. Experimental microbiology, Patel and Patel, Educreation publishing,2019
4. Biochemistry of antimicrobial action, Franklin T.J. and Snow G A., Chapman and Hall London, 1975
5. The basic pharmacology- Goldsmith A. Aronow L. Kalman S.M., Harper international edition, New York, 1969
6. Pharmacology , Kokate C K, Purohit A P, Gokhale A. B. Nirali prakashan 4th edition, , 2000.

Semester VI

CT VI: DMIT 606: `Microbiological quality control in pharmaceutical industry II`

(Contact Hrs: 30 Credits: 2)

Learning Objectives: Students will be able to

1.Understand aseptic techniques, Pharmacopeia and microbiological tests and environmental monitoring
2. Study about Microbial count, units of measurement and methods of bio burden assessment

Unit I- Testing of pharmaceutical products 15

Microbiology laboratory techniques: Introduction, Good laboratory practice and laboratory safety, Aseptic technique, Cultures and identifications, Microscopy, Pharmacopeia and microbiological tests, Microbiological examination of nonsterile products, Measurement of cell concentration in suspension by optical density, Sterility testing, In vitro and in vivo testing for pyrogens and endotoxins, Microbiological assay of antibiotics, Environmental monitoring, Water analysis

Unit II- Bio burden determination 15

Microbial count, Units of measurement, Non sterile products and microbial limits testing, In-process material bioburden assessment, Presterilization bio burden assessment, Alternative methods of bio burden assessment

Learning Outcomes: After completion of units**,** student should able to-

1. Understand aseptic techniques, Pharmacopeia and microbiological testing and environmental monitoring
2. Explain the concept of counting of microbes, units of measurement and methods of bio burden assessment

References:

1. Handbook of microbiology quality control, Norman A Hodges and Stephen P. Denyer. 8th edition, 2019
2. Pharmaceutical microbiology, W.B. Hugo and A.D. Russell, 7th edition , 2009
3. Basic experimental microbiology , Ronald M. atlas, Alfred E. Brown, Macmillan,1986
4. Harper's handbook of Therapeutic pharmacology, R.Marilyn Schmidt, Solomon Margolin,Harper and Row ,1981
5. Biochemistry of antimicrobial action, T. J. Franklin and G.A. Snow, Chapman and Hall, London, 2nd edition, 1971.
6. Microbial quality assurance in pharmaceuticals, Cosmetics and Toiletries,R.Baird and Sally F. Bloomfield, CRC press, 2nd edition, 1996
7. Pharmaceutical quality control Microbiology- A guide Book to the basics, Scott Sutton,Pda,1st edition,2007
8. Pharmaceutical microbiology,Saluja A.K., Purohit S.S., Kalkrani H.N.,Agrobios publication.
9. Industrial, Pharmaceutical microbiology, I Standard and control editors- Doctor N. Hodge
10. Pharmaceutical Microbiology, Essentials for quality control and quality assurance, Tim Sandle, Wood head publishing, Elsevier, 2016

:

CT VI:**DMIL606**: **Practical**

(Contact Hrs: 60 Credits: 02)

Learning Objectives: Students will be able to

1. Understand Microbiological analysis of Air and bacteriological analysis of water.
2. Understand sterility testing of nutrient broth, surgical gauze, and surgical cotton.
3. Study microbial analysis of different products.
4. Study microbial load of non sterile product

List of Practical's (15)

1. Microbiological analysis of Air
2. Bacteriological analysis of water- MPN

3. Presumptive test of water
4. Confirm test of water
5. Completed test of water
6. Sterility testing by Bacillus stearothermophilus
7. Sterility testing of a sterile powder using nutrient broth / fluid thyoglycolate
8. Sterility testing of surgical gauze
9. Sterility testing of surgical cotton
10. Microbial Limit Test
11. Identification of bacteria using specialized media
12. Microbiological analysis of Equipments&personels.
13. Microbiological analysis of Raw materials & finished products.
14. Microbiological analysis of spoiled pharmaceutical products- SPC
15. Determination of microbial load of non-sterile products- Ointment, capsule

Learning Outcomes: After completion of practical course, student should able to-

1. Perform Microbiological analysis of Air and bacteriological analysis of water.
2. Perform sterility testing of nutrient broth, surgical gauze, and surgical cotton.
3. Understand microbial analysis of different products.
4. Determine Microbial load of non-sterile product

References:

1. Introduction to practical biochemistry, David T. Plummer, McGraw-Hill Book Company (U.K) Ltd., London, Volume 6, 1978.
2. Laboratory Manual in Microbiology, P. Gunasekaran, New age International(P) Ltd, First Edition,1995.
3. Experimental microbiology, Patel and Patel, Educreation publishing,2019
4. Biochemistry of antimicrobial action, Franklin T.J. and Snow G A., Chapman and Hall London, 1975
5. The basic pharmacology- Goldsmith A. Aronow L. Kalman S.M., Harper international edition, New York, 1969
6. Pharmacology, Kokate C K, Purohit A P, Gokhale A. B. Nirali prakashan 4th edition, , 2000.

CP III:DMIP303(Project):
(Contact Hrs.60, Credits: 2)
Industrial or Incubation or Field Training is compulsory

BOS subcommittee:
1.Mrs.G.V.Utekar, Chairman
2.Ms.P.V. Mali, Member

Expert:
1.Dr.Bharat Ballal,Asso.Professor,Dr.Patangrao Kadam Mahavidyalaya,Sangali- Academic expert
2.Mr.Sandip Babar, Industrial Expert