

**DISCIPLINE SPECIFIC ELECTIVE COURSE – 3:
MICROBIAL QUALITY CONTROL IN FOOD AND PHARMACEUTICAL INDUSTRIES**

CREDIT DISTRIBUTION, ELIGIBILITY AND PRE-REQUISITES OF THE COURSE

| Course title & Code | Credits | Credit distribution of the course | | | Eligibility criteria | Pre-requisite of the course (if any) |
|--|----------|-----------------------------------|----------|----------------------|--|--------------------------------------|
| | | Lecture | Tutorial | Practical / Practice | | |
| MICROB-DSE 3: MICROBIAL QUALITY CONTROL IN FOOD AND PHARMACEUTICAL INDUSTRIES | 4 | 2 | 0 | 2 | Class XII pass with Biology/ Biotechnology / Biochemistry | NIL |

Learning Objectives

The Learning Objectives of this course are as follows:

- The main objective of this course is for students to develop an understanding of the concept and implementation of microbial quality control in the food and pharmaceutical industries.
- Students will gain insights into how the final products obtained for human and animal consumption are consistent, certified as safe for human consumption, and compliant with microbial standards.

Learning outcomes

The Learning Outcomes of this course are as follows:

- Student will be able to describe the parameters and techniques of Good Laboratory and Microbiological practices, sources of contamination, microbial monitoring of the environment and the concept of clean areas in the industry.
- Student will be able to explain the techniques of collecting and processing food, water and pharmaceutical samples for bioburden testing, various microscopic, culturing, biochemical, molecular and immunological testing techniques used for assessing the presence of microbes/pathogens as well as the toxic microbial products.
- Student will be able to describe Total Quality Management (TQM) system and Standard Operating Procedures (SOP) for fulfilling the requirements of Quality

Control (QC) are created, various microbiological standards and certifications by accrediting bodies for food and pharmaceutical industries.

- Student will be able to demonstrate the techniques for checking milk quality by performing rapid and standard laboratory tests, method of testing of microbiological quality of water samples (Most Probable Number).
- Student will be able to describe how the food sample is processed for the detection of microorganisms, various differential and selective media to detect and identify different microorganisms present in a food sample.
- Student will be able to demonstrate sterility testing of various food and pharmaceutical products under different conditions.
- Student will be able to develop HACCP flow charts for different products, the application of various standards in quality regulation in food and pharma products with the help of case studies.

Contents:

Theory:

30 hours

Unit 1. (8 hours)

Microbiological safe practices for food and pharmaceutical industry: Laboratory practices for safety and quality (GLP and GMLP). Concept of Biosafety cabinets. Biosafety

levels (BSL-I to BSL-IV): designs, specifications and uses. Concept of Clean Area and its classification. Microbial monitoring of controlled environments (bioburden). Sources of contamination in food and pharmaceutical industries. Steps to avoid contamination. Food Safety, Sanitation Standard Operating Procedure (SSOP) and Personal Hygiene.

Unit 2: (14 hours)

Monitoring and analysis of microbiological quality of food and pharmaceutical samples: Types of products in food and pharmaceutical industries. Bioburden testing for food, beverages and medical devices. Collection and processing of samples for microbiological monitoring. Detection of microorganisms by microscopic method (fluorescence-based Direct Microscopic Count). Detection of microorganisms by cultural methods: enrichment technique, standard plate count, the concept of differential and selective media for detection of pathogens (XLD agar, Salmonella-Shigella agar, Mannitol salt agar, EMB agar, McConkey agar). Microbiological examination of non-sterile pharmaceutical products, concept of microbial limits, sterility testing (its objectives and significance). Molecular, biochemical and immunological methods for detection of microorganisms and their products (Nucleic acid probes, PCR, biosensors, Limulus lysate test, pyrogen testing). Significance of rapid detection methods (Clot on

Boiling Test, dye reduction test by Resazurin) in food industry.

Unit 3: (8 hours)

Microbial quality standards and management: Introduction and importance of quality standards. Concepts and approaches of Total Quality Management (TQM), Quality Management System, ISO 9001:2000, Quality Assurance and Quality Control. Development of Standard Operating Procedures. Hazard analysis of critical control point (HACCP): principles, applications and limitations. Concept of Codex Alimentarius and Codex Standards. Role of accredited certification bodies (BIS, Agmark, FSSAI, ISO) in maintaining product quality.

Practicals:

60 hours

Unit 1: (20 hours)

Testing of quality of milk and water samples: Checking the effectiveness of pasteurization of milk: Alkaline phosphatase test. Detection of microbiological quality of milk sample through Triphenyltetrazolium chloride (TTC) test, Clot on boil (COB) test and dye reduction test (Resazurin). Determination of microbiological quality of water sample by MPN method.

Unit 2: (30 hours)

Microbiological quality of food and pharmaceutical products: Sample processing for detection of microorganisms in food (one solid: Bread/idli batter/cheese/biscuits/ pizza base/salad/cake etc. and one liquid:juice/ butter milk/ energy drink etc. sample/s.) Detection and Identification of microorganisms present in processed food samples through different types of media (XLD agar/Salmonella-Shigella agar, Mannitol salt agar, EMB agar, McConkey agar). Sterility testing of food (canned food/tetrapak drink) and pharmaceutical products (eye drops/injection ampoule) for aerobic microbes using cultural methods. Demonstration to test the presence of anaerobic microbes by virtual lab/video .Principle and concept of Limulus lysate (LAL) test for detecting the presence of endotoxin in consumable products by virtual lab/video.

Unit 3: (10 hours)

Quality regulation of food and pharmaceutical products: Study of HACCP of milk/dairy product with the help of flow chart. **Student group project:** applications of various standards (BIS, Agmark, FSSAI, ISO) in quality regulation in food and pharma products: case studies involving at least one food and one pharma product.

Suggested Reading (Theory & Practical):

1. Analytical Food Microbiology: A Laboratory Manual by A.E. Yousef, J.G. Waite-Cusic and J.J. Perry. 2nd edition. Wiley Publishers, UK. 2022.
2. Essentials of Pharmaceutical Microbiology by A. Kar, 2nd edition. New Age International. India. 2020.
3. Food Safety and Quality Control by P. Mathur. 1st edition. The Orient Blackswan, India. 2018.
4. Pharmaceutical Biotechnology: Fundamentals and Applications by J.A.D. Crommelin, R. D. Sindelar, and B. Meibohm.(Eds.) 4th edition. Springer, Germany. 2016.
5. Manuals of methods of analysis of foods and water by Food Safety and Standards Authority of India, Ministry of health and family welfare, Government of India, 2016.
https://old.fssai.gov.in/Portals/0/Pdf/Draft_Manuals/WATER.pdf
https://old.fssai.gov.in/Portals/0/Pdf/Manual_Fruits_Veg_25_05_2016.pdf
6. Pharmaceutical Microbiology: Essentials for quality assurance and quality control by T. Sandle. 1st edition. Woodhead Publishing. UK. 2015.
7. Fundamentals of Food Microbiology by Bibek Ray and A. Bhunia. 5th edition. CRC Press UK. 2013.
8. Pharmaceutical Biotechnology: Concepts and Applications by G. Walsh. 1st edition. John Wiley & Sons Ltd. USA. 2011.
9. Modern Food Microbiology by J.M. Jay, M.J. Loessner and D.A. Golden. 7th edition. CBS Publishers and Distributors, India. 2006.
10. Handbook of Microbiological Quality control in Pharmaceutical and Medical Devices. R.M Baird, N.A Hodges, and S.P Denyer (Eds) 2nd edition. Taylor and Francis Inc., USA. 2005.
11. Hugo and Russell's Pharmaceutical Microbiology by S.P. Denyer, N.A. Hodges and S.P. Gorman. 7th edition. Blackwell Science. 2004.
12. Microbiological Analysis of Food and Water: Guidelines for Quality Assurance by N.F. Lightfoot and E.A. Maier. 1st edition. Elsevier Science. 1998.
13. Quality control in the Pharmaceutical Industry by M.S. Cooper (Ed). Vol.2. Academic Press,USA.1974.

Note: Examination scheme and mode shall be as prescribed by the Examination Branch, University of Delhi, from time to time.