

# DEPTH OF BIOLOGY - Level up your studies with DOB

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B.Pharm Syllabus

## Semester III

| Course Code    | Name of the course                                                   |                                     | No. of hours per week (L/P) | Credit points |
|----------------|----------------------------------------------------------------------|-------------------------------------|-----------------------------|---------------|
| BP301T         | Introduction to Machine Learning in Pharmaceutical Sciences (Theory) |                                     | 2                           | 2             |
| BP302T         | Environmental Sciences (Theory)                                      |                                     | 1                           | 1             |
| BP303T         | Ethics and Universal Human Values (Theory)                           |                                     | 1                           | 1             |
| BP304T         | General Pharmacology (Theory)                                        |                                     | 3                           | 3             |
| BP305T         | Heterocyclic Compounds and Stereochemistry (Theory)                  |                                     | 3                           | 3             |
| BP306T         | Pharmaceutical Dosage Forms I (Theory)                               |                                     | 3                           | 3             |
| BP307T         | Pharmaceutical Engineering (Theory)                                  |                                     | 3                           | 3             |
| BP308T         | Pharmaceutical Microbiology (Theory)                                 |                                     | 3                           | 3             |
| BP309P         | General Pharmacology (Practical)                                     |                                     | 4                           | 2             |
| BP310P         | Heterocyclic Compounds and Stereochemistry (Practical)               |                                     | 4                           | 2             |
| BP311P         | Pharmaceutical Dosage Forms I (Practical)                            |                                     | 3                           | 1             |
| BP312P<br>AEC* | BP312P<br>AEC1                                                       | Nutraceuticals and Functional Foods | 2                           | 1             |
|                | BP312P<br>AEC2                                                       | Food Analysis                       |                             |               |
|                | BP312P<br>AEC3                                                       | Yoga and Life Sciences              |                             |               |
| <b>Total</b>   |                                                                      |                                     | <b>32</b>                   | <b>25</b>     |

\* Only 1 elective course shall be selected

The syllabi for elective subjects are given in the *appendix*

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| Course Code   | Course Title                                                                |    |    | Course Type |
|---------------|-----------------------------------------------------------------------------|----|----|-------------|
| BP301T        | <b>Introduction to Machine Learning in Pharmaceutical Sciences (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                                                      |    |    | Max. Hours  |
|               | L                                                                           | T  | P  |             |
| 2             | 2                                                                           | -- | -- | 30          |
| Maximum Marks | SE                                                                          |    |    | ESE         |
| 50            | 20                                                                          |    |    | 30          |

## COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts of Artificial Intelligence, Machine Learning, and Data Science and their relevance to pharmaceutical sciences.
2. Develop conceptual understanding of machine learning workflows, including model building, training–testing strategies, and evaluation.
3. Explain the principles and applications of regression models for predicting continuous outcomes in pharmaceutical and healthcare data.
4. Familiarize students with classification and tree-based models used for clinical prediction and decision-making.
5. Introduce unsupervised learning techniques and demonstrate their applications in pattern recognition and healthcare data analysis.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to:                                                                         |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Explain the basic concepts of artificial intelligence and machine learning, including types of learning and model development.                   |
| 2      | Apply regression models to analyze pharmaceutical data and interpret model outputs and performance metrics.                                      |
| 3      | Analyze classification models for predicting categorical clinical outcomes using evaluation measures such as accuracy, sensitivity, and ROC–AUC. |
| 4      | Interpret tree-based and ensemble learning models for decision-making in pharmaceutical and healthcare applications.                             |
| 5      | Utilize unsupervised learning techniques such as clustering to identify patterns in healthcare and pharmaceutical datasets.                      |

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## Detailed Syllabus:-

| Unit No. | Topics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No. of Lectures |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <b>Foundations of Machine Learning</b><br>Definition and scope of Artificial Intelligence, Machine Learning, and Data Science <ul style="list-style-type: none"> <li>Types of machine learning: supervised, unsupervised, and reinforcement learning</li> <li>Features and labels, training data and testing data</li> <li>Concept of model building and prediction</li> <li>Train-test split, overfitting and underfitting</li> <li>Conceptual explanation of bias-variance trade-off</li> <li>Overview of the basic ML workflow</li> </ul>                                                                                                                                                                                                                                           | 6 Hours         |
| II       | <b>Regression Models in Healthcare</b><br>Overview of the concepts in predictive modeling for continuous outcomes, with emphasis on interpretation of outputs, and applications in pharmaceutical sciences. <ul style="list-style-type: none"> <li>Linear regression and multiple linear regression</li> <li>Model coefficients and their interpretation</li> <li>Residuals and goodness-of-fit</li> <li>Performance metrics such as Mean Squared Error (MSE), Root Mean Squared Error (RMSE), <math>R^2</math> score</li> <li>Implementation of regression models on pharmaceutical data ( e.g. dose–response relationships, predicting drug dissolution rates, estimating PK parameters), and demonstration of predictive modeling using python libraries such as sklearn</li> </ul> | 6 Hours         |
| III      | <b>Classification Models in Clinical Applications</b><br>Overview of the following ML models used for categorical prediction, with emphasis on conceptual understanding, interpretation of outputs and applications in pharmaceutical sciences. <ul style="list-style-type: none"> <li>Logistic regression</li> <li>Probability output and threshold selection</li> <li>Confusion matrix</li> <li>Accuracy, sensitivity, specificity, precision, recall</li> <li>Intuitive understanding of ROC curve and AUC, and k-Nearest Neighbors</li> <li>Demonstration of predictive modeling using pharmaceutical and clinical examples such as predicting adverse drug reactions, disease risk prediction, binary therapeutic outcome modeling.</li> </ul>                                    | 6 Hours         |

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| IV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p><b>Tree-Based Models &amp; Ensemble Learning</b></p> <p>Overview of the following ML models with emphasis on intuitive and conceptual understanding.</p> <ul style="list-style-type: none"> <li>• Decision Trees (structure and splitting criteria), interpretation of decision paths and feature importance</li> <li>• Random Forest, overview of ensemble concept</li> <li>• Advantages and limitations of tree-based models</li> <li>• Demonstration of these models for pharmaceutical and clinical applications such as ADR risk stratification, Patient classification, Predicting treatment outcomes etc.</li> </ul>                         | 6 hours |
| V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p><b>Unsupervised Learning &amp; Practical Case Studies</b></p> <p>Overview of the unsupervised learning with emphasis on intuitive and conceptual understanding of pattern recognition and clustering, and their applications in pharmaceutical sciences.</p> <ul style="list-style-type: none"> <li>• Concept of unsupervised learning</li> <li>• Clustering overview, K-means clustering, choosing number of clusters, Interpreting cluster outputs</li> <li>• Mini-case study integrating regression, classification, or clustering on healthcare datasets to demonstrate Patient segmentation, and drug grouping based on properties.</li> </ul> | 6 Hours |
| <p><b>Recommended References (Preferably latest editions):</b></p> <ol style="list-style-type: none"> <li>1. James, G., Witten, D., Hastie, T. and Tibshirani, R. <i>An Introduction to Statistical Learning with Applications in Python</i>. Springer. Available at: statlearning.com.</li> <li>2. Simon, G. J. and Aliferis, C. <i>Artificial Intelligence and Machine Learning in Health Care and Medical Sciences: Best Practices and Pitfalls</i>. Springer.</li> <li>3. Brown, N. <i>Artificial Intelligence in Drug Discovery</i>. Royal Society of Chemistry.</li> <li>4. Walters, S. J., Campbell, M. J. and Machin, D. <i>Medical Statistics: A Textbook for the Health Sciences</i>. Wiley-Blackwell.</li> <li>5. Géron, A. <i>Hands-On Machine Learning with Scikit-Learn, Keras and TensorFlow</i>. O'Reilly Media.</li> </ol> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |

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| Course Code   | Course Title                           |    |    | Course Type |
|---------------|----------------------------------------|----|----|-------------|
| BP302T        | <b>Environmental Sciences (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                 |    |    | Max. Hours  |
|               | L                                      | T  | P  |             |
| 1             | 1                                      | -- | -- | 15          |
| Maximum Marks |                                        | SE |    | ESE         |
| 50            |                                        | 20 |    | 30          |

## COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the environmental challenges and disaster risks relevant to human health and pharmaceutical activities.
2. Demonstrate knowledge of waste management protocols and legal guidelines for pharmaceutical and biomedical waste handling.
3. Apply technical understanding of effluent and sewage treatment technologies used in the pharmaceutical sector.
4. Assess the ecological impact of APIs and recommend mitigation strategies for pollution control.
5. Explain sustainable practices and energy-efficient operations within pharmaceutical industries.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to                                                                                   |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Understand the basic concepts of environmental pollution, its types, causes, and disaster management strategies.                                          |
| 2      | Identify and categorize different types of pharmaceutical and biomedical waste generated in the healthcare and pharmaceutical sectors.                    |
| 3      | Describe the design and operation of Effluent Treatment Plants (ETPs), Sewage Treatment Plants (STPs), and water purification systems in pharma settings. |
| 4      | Analyze the environmental risks posed by pharmaceutical manufacturing, APIs, and dosage forms.                                                            |
| 5      | Recognize the importance of sustainability and green pharmacy practices in the pharmaceutical industry.                                                   |

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## Detailed Syllabus:

| Unit No.                                                                                                                                                                                                                                                                                                                                              | Topics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | No. of Lectures |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I                                                                                                                                                                                                                                                                                                                                                     | <b>Environmental Pollution</b> <ul style="list-style-type: none"> <li>Definition, scope, and importance of environmental studies</li> <li>Types, causes, effects, and control measures of Air, water, soil, noise, and nuclear pollution</li> <li>Solid waste and hazardous waste management in pharmaceuticals</li> <li>Role of pharmacists in conservation and sustainable use of resources</li> </ul>                                                                                                                                                                           | 3 Hours         |
| II                                                                                                                                                                                                                                                                                                                                                    | <b>Pharmaceutical Waste and Effluent Management</b> <ul style="list-style-type: none"> <li>Types of pharmaceutical waste: chemical, expired drugs, packaging, biomedical waste</li> <li>Biomedical Waste Management Rules (2016) and CPCB guidelines</li> <li>Effluent Treatment Plant (ETP) design and functioning</li> <li>Water purification methods in pharmaceutical settings (RO, UV, distillation, filtration)</li> </ul>                                                                                                                                                   | 3 Hours         |
| III                                                                                                                                                                                                                                                                                                                                                   | <b>Environmental Impact of the Pharmaceutical Industry</b> <ul style="list-style-type: none"> <li>Sources of pollution in pharmaceutical manufacturing</li> <li>Types of pharmaceutical waste: solid, liquid, and gaseous</li> <li>Environmental risks of active pharmaceutical ingredients (APIs) and its dosage forms.</li> <li>Impact of pharmaceutical residues on ecosystems and human health</li> </ul>                                                                                                                                                                      | 3 Hours         |
| IV                                                                                                                                                                                                                                                                                                                                                    | <b>Sustainability in the Pharmaceutical Sector</b> <ul style="list-style-type: none"> <li>Principles of sustainable development in pharma</li> <li>Principles and Practices of Green pharmacy</li> <li>Energy conservation and resource optimization.</li> </ul>                                                                                                                                                                                                                                                                                                                   | 3 Hours         |
| V                                                                                                                                                                                                                                                                                                                                                     | <b>Government Policies, Compliance, and Practical Exposure</b> <ul style="list-style-type: none"> <li>Environmental laws: <ul style="list-style-type: none"> <li>Environment (Protection) Act, 1986</li> <li>Water (Prevention and Control of Pollution) Act</li> </ul> </li> <li>National Green Tribunal (NGT) and regulatory bodies (CPCB, SPCB)</li> <li>Government initiatives: <ul style="list-style-type: none"> <li>Swachh Bharat Abhiyan</li> <li>River rejuvenation program- Namami Gange Programme</li> <li>Jal Jeevan Mission</li> </ul> </li> <li>ISO-14000</li> </ul> | 3 Hours         |
| <b>Recommended References (Preferably latest editions):</b> <ol style="list-style-type: none"> <li>Bharucha, E. <i>Environmental Studies</i>. University Grants Commission, New Delhi.</li> <li>Rajagopalan, R. <i>Environmental Studies</i>. Oxford University Press.</li> <li>Joseph, B. <i>Environmental Studies</i>. Tata McGraw Hill.</li> </ol> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                 |

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| Course Code   | Course Title                                      |    |    | Course Type |
|---------------|---------------------------------------------------|----|----|-------------|
| BP303T        | <b>Ethics and Universal Human Values (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                            |    |    | Max. Hours. |
|               | L                                                 | T  | P  |             |
| 1             | 1                                                 | -- | -- | 15          |
| Maximum Marks | SE                                                |    |    | ESE         |
| 50            | 20                                                |    |    | 30          |

## COURSE OBJECTIVES:

The objectives of this course are:

1. Understand the concept, definition, scope, and need of Value Education in personal, social, and professional life.
2. Develop self-exploration, positive attitude, confidence, and ethical sensitivity as foundations of value-based living.
3. Comprehend the co-existence of Self (I) and Body and establish harmony between physical and psychological aspects.
4. Analyze the importance of family, society, and relationships in promoting mutual respect, trust, and cooperation.
5. Appreciate the concept of harmony in nature and existence, leading to sustainable and responsible human conduct.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to:                                                                   |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Explain the principles, content, and process of Value Education and apply ethical values in day-to-day life.                               |
| 2      | Demonstrate self-awareness, right understanding, confidence, and clarity about happiness and prosperity through self-exploration.          |
| 3      | Distinguish between the needs and activities of the Self and the Body and establish harmony between them.                                  |
| 4      | Apply values such as respect, affection, kindness, gratitude, and love to maintain harmony in family and society.                          |
| 5      | Interpret the concept of harmony in nature and holistic existence, recognizing the four orders of nature and the comprehensive human goal. |

## Detailed Syllabus:

| Unit No. | Topics                                                                                                                                                                                            | No. of Lectures |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <b>Introduction to Value Education</b><br>1. Concept, definition, and need for value education.<br>2. Content and process of value education.<br>3. Application of human values in everyday life. | 3 Hours         |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>II</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Self-Exploration and Human Aspirations</b><br>1. Self-exploration as a means of value education.<br>2. Development of positive attitude and self-confidence.<br>3. Right understanding of happiness and prosperity.                                                                                                                                                                       | 3 Hours |
| <b>III</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Harmony in the Human Being</b><br>1. Human being as more than just the physical body.<br>2. Harmony between the Self ('I') and the Body.<br>3. Understanding the coexistence of the Self and the Body.                                                                                                                                                                                    | 3 Hours |
| <b>IV</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Harmony in the Individual and Society</b><br>1. Understanding the needs of the Self and the needs of the Body.<br>2. Activities of the Self and activities of the Body.<br>3. Family as the basic unit of human interaction and the role of values in relationships.<br>4. Foundations of respect in relationships: affection, kindness, guidance, reverence, glory, gratitude, and love. | 3 Hours |
| <b>V</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Harmony in Society and Nature</b><br>1. Comprehensive human goal: the five dimensions of human endeavour.<br>2. Harmony in nature and the four orders in nature.<br>3. Holistic perception of harmony in existence.                                                                                                                                                                       | 3 Hours |
| <b>Recommended References (Preferably latest editions):</b><br>1. Tripathi, A. N. <i>Human Values</i> . New Age International Publishers, New Delhi.<br>2. Gaur, R. R., Asthana, R. and Bagaria, G. P. <i>A Foundation Course in Human Values and Professional Ethics</i> . Excel Books, New Delhi.<br>3. Gaur, R. R., Asthana, R. and Bagaria, G. P. <i>Teachers' Manual for A Foundation Course in Human Values and Professional Ethics</i> . Excel Books, New Delhi.<br>4. Raghavan, V. <i>Universal Human Values</i> . Excel Books.<br>5. Gaur, R. R., Sangal, R. and Bagaria, G. P. <i>Human Values and Professional Ethics</i> . Excel Books.<br>6. Govindarajan, M., Natarajan, S. and Senthil Kumar, V. S. <i>Engineering Ethics</i> . Prentice Hall India.<br>7. Velasquez, M. G. <i>Business Ethics: Concepts and Cases</i> . Pearson Education. |                                                                                                                                                                                                                                                                                                                                                                                              |         |

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| Course Code   | Course Title                         |    |    | Course Type |
|---------------|--------------------------------------|----|----|-------------|
| BP304T        | <b>General Pharmacology (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)               |    |    | Max. Hours. |
|               | L                                    | T  | P  |             |
| 3             | 3                                    | -- | -- | 45          |
| Maximum Marks | SE                                   |    |    | ESE         |
| 75            | 30                                   |    |    | 45          |

## COURSE OBJECTIVES:

The objectives of this course are:

1. To provide a foundational understanding of the history of pharmacology, focusing on the evolution of drug discovery and development.
2. Introducing the concepts of pharmacodynamics and pharmacokinetics, helping students understand the mechanisms of drug action, absorption, distribution, metabolism, and excretion.
3. To familiarize students with the principles behind new drug development, including preclinical testing, drug screening methods, and safety pharmacology.
4. To enable students to learn about toxicity testing, ensuring they understand different methods of evaluating drug safety and the regulatory guidelines involved in toxicity assessment.
5. To prepare students for understanding the pharmacology of different therapeutic drug classes, by applying basic pharmacological knowledge to current trends in drug development and screening.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to                                                                                             |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Relate the fundamental principles of pharmacodynamics and pharmacokinetics of drugs actions on the human body.                                                      |
| 2      | Illustrate the processes involved in the drug metabolism, toxicity, and safety evaluation to relate their significance in the preclinical development of new drugs. |
| 3      | Apply the knowledge of pharmacological principles to efficacy, toxicity, and safety evaluation of new drug candidates.                                              |
| 4      | Assess the ethical and scientific principles underlying drug safety, efficacy, and toxicity testing                                                                 |
| 5      | Appraise the recent trends in pharmacology.                                                                                                                         |

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## Detailed Syllabus:

| Unit No. | Topics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | No. of Lectures |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <b>Introduction to Pharmacology</b><br>a) Definition, historical perspectives, branches of pharmacology and their scope, drug, nature and sources of drugs, International Classification of Diseases (ICD) and International Non-proprietary Names (INN) for drugs<br>b) Concept of generic medicines, essential drugs and rational drug use (RDU). Indian Government's initiatives to promote these concepts.<br>c) Routes of drug administration along with their advantages and disadvantages.                                                                                                                                                                                                   | 08 Hours        |
| II       | <b>Pharmacokinetics</b><br>a) Drug absorption, mechanisms of drug absorption, membrane transporters, bioavailability, bioequivalence, factors affecting drug absorption.<br>b) Drug distribution in different compartments, volume of distribution, storage sites, plasma protein binding and its therapeutic importance.<br>c) Drug biotransformation, microsomal, non- microsomal metabolism and cytochrome P450 enzyme system, phase I and II reactions, first-pass metabolism, entero-hepatic cycling, concept of prodrugs.<br>d) Drug excretion and its kinetics.                                                                                                                              | 07 Hours        |
| III      | <b>Pharmacodynamics</b><br>a) Types drug action and mechanisms of drug action, dose response relationship.<br>b) Receptor theories, structure of receptors, classification and regulation of receptors, spare receptors. Concept of agonist, inverse agonist, partial agonist and antagonist.<br>c) Signal transduction mechanisms of receptors.<br>d) Factors modifying drug action including the concepts of tachyphylaxis, idiosyncrasy, drug tolerance, dependence, addiction, and the combined effect of drugs (Additive effect & Synergism).<br>e) Adverse drug reactions (ADR) and types of ADRs.<br>f) Drug interaction, types, pharmacokinetic and pharmacodynamic drug-drug interactions. | 10 Hours        |
| IV       | <b>Overview of drug discovery and evaluation of new drug</b><br>a) Brief discussion on drug discovery and preclinical evaluation of new drugs.<br>b) Human relevant screening techniques: Reconstructed human epidermis, organ-on- Chip model, skin irritancy test by reconstructed corneal epithelium, skin corrosivity testing by Direct                                                                                                                                                                                                                                                                                                                                                          | 12 Hours        |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>Peptide Reactivity Assay.</p> <p>c) Advantages and disadvantages of <i>in vitro</i> and <i>in silico</i> Pharmacological screening and evaluation</p> <p><b>Recent trends in pharmacology</b></p> <p>a) Chronopharmacology: Introduction, biological clock, types of rhythms, hormones, diseases and drugs affected by circadian rhythm. Introduction to chrono kinetics and importance of chronotherapeutic and future scope.</p> <p>b) Introduction, general principles, applications and scope of Pharmacogenomics, Gene therapy, Biosimilars and Precision medicine.</p>                                                                                    |         |
| V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p><b>Toxicology</b></p> <p>a) Introduction to toxicology and its branches. Classification of poisons based on actions and lethal doses, types of antidotes.</p> <p>b) General principles of treatment of acute poisoning include heavy metal poisoning. Management of poisoning.</p> <p>c) Definition and basic knowledge of preclinical toxicity testing-acute toxicity, sub-acute toxicity, combined chronic and carcinogenicity testing as per OECD norms.</p> <p>d) Basic understanding of principles of genotoxicity and teratogenicity as per OECD guidelines.</p> <p>e) Definition and concepts of safety pharmacology as per ICH and OECD guidelines.</p> | 8 Hours |
| <p><b>Recommended References (Preferably latest editions):</b></p> <ol style="list-style-type: none"> <li>1. Brunton, L., Hilal-Dandan, R. and Knollmann, B. <i>Goodman and Gilman's The Pharmacological Basis of Therapeutics</i>. McGraw-Hill Education.</li> <li>2. Rang, H. P., Dale, M. M., Ritter, J. M., Flower, R. J. and Henderson, G. <i>Rang and Dale's Pharmacology</i>. Elsevier.</li> <li>3. Katzung, B. G. and Trevor, A. J. <i>Basic and Clinical Pharmacology</i>. McGraw-Hill Education.</li> <li>4. Whalen, K. and Finkel, R. <i>Lippincott's Illustrated Reviews: Pharmacology</i>. Wolters Kluwer.</li> <li>5. Tripathi, K. D. <i>Essentials of Medical Pharmacology</i>. Jaypee Brothers Medical Publishers.</li> </ol> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |

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| Course Code   | Course Title                                                |    |    | Course Type |
|---------------|-------------------------------------------------------------|----|----|-------------|
| BP305T        | <b>Heterocyclic Compounds and Stereo Chemistry (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                                      |    |    | Max. Hours. |
|               | L                                                           | T  | P  |             |
| 3             | 3                                                           | -- | -- | 45          |
| Maximum Marks | SE                                                          |    |    | ESE         |
| 75            | 30                                                          |    |    | 45          |

## COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand Chemistry of Carboxylic acids, Phenols, Amines and Polynuclear Aromatic hydrocarbons
2. Explain the concepts of optical isomerism and their pharmaceutical significance.
3. Explain the concepts of Geometrical isomerism and their pharmaceutical significance
4. Know about IUPAC nomenclature and Chemistry of heterocycles
5. Equip students with knowledge of organic reaction mechanisms and their applications in drug synthesis.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to:                                                                            |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Recall and outline methods for the preparation and chemical reactions of various organic compounds.                                                 |
| 2      | Explain the acidity and basicity of organic compounds and recognize the medicinal relevance of polynuclear hydrocarbons and heterocyclic compounds. |
| 3      | Illustrate the concepts of stereoisomerism with appropriate examples.                                                                               |
| 4      | Classify, name, and interpret the structures and chemistry of heterocyclic compounds.                                                               |
| 5      | Describe and analyze the synthesis, chemical behaviour, and applications of heterocyclic and polynuclear hydrocarbon compounds.                     |

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## Detailed Syllabus:

| Unit No. | Topics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | No. of Lectures |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <p><b>Chemistry of Carboxylic acids, Phenols, Amines and Polynuclear Aromatic hydrocarbons</b></p> <ol style="list-style-type: none"> <li><b>Aliphatic and aromatic carboxylic acids</b> <ul style="list-style-type: none"> <li>Methods to prepare carboxylic acids (Oxidation of alcohols, carbonation of Grignard reagent, Kolbe-Schmidt reaction)</li> <li>Study of acidity of carboxylic acids and effect of substituents on acidity</li> <li>Study of chemical reactions of carboxylic acids [Mechanism of nucleophilic acyl substitution, Decarboxylation and Hell-Volhard-Zelinsky reaction]. Pharmaceutical applications of aromatic carboxylic acids (Benzoic acid, Salicylic acid, Acetyl Salicylic acid)</li> </ul> </li> <li><b>Aliphatic and aromatic amines</b> <ul style="list-style-type: none"> <li>Methods to prepare amines (Reduction of nitro compound, reduction of nitriles and Hofmann degradation of amides)</li> <li>Study of basicity of amines and effect of substituents on basicity</li> <li>Study of mechanism and synthetic applications of diazonium salts including Sandmeyer's and azo-dye coupling reaction</li> </ul> </li> <li><b>Alcohols and Phenols</b> <ul style="list-style-type: none"> <li>Classification of alcohols, methods to prepare alcohols (oxymercuration - demercuration, reduction of carbonyl compounds)</li> <li>Acidity of alcohols and Phenols including effect of substituent on acidity</li> <li>Definition of phenols, method to prepare phenols by cumene process. Comparison of the acidity of phenol vs alcohol</li> <li>Study of mechanism of chemical reactions of phenols (Reimer-Tiemann reaction, halogenation and nitration of phenols). Pharmaceutical applications of alcohols and phenols (Glycerine, Thymol, Paracetamol)</li> </ul> </li> <li><b>Chemistry of polynuclear aromatic hydrocarbons</b> <p>Definition, and classification of polynuclear aromatic hydrocarbons, Study of synthesis (Haworth synthesis) and mechanism of electrophilic aromatic substitution reactions of naphthalene, phenanthrene and anthracene and medicinal uses of drugs containing Naphthalene (Propranolol, Naphazoline) and Phenanthrene (Morphine, Codeine).</p> </li> </ol> | 15 Hours        |
| II       | <p><b>Optical isomerism</b></p> <ul style="list-style-type: none"> <li>Definition of stereoisomerism and types of stereoisomerism with examples</li> <li>Definition with examples for optical activity, origin of chirality, elements of symmetry, chiral and achiral molecules, enantiomerism, diastereoisomerism and meso compounds</li> <li>Study of configuration including D &amp; L system, sequence rules, R &amp; S system. Medicinal importance of optical isomers with examples</li> <li>Racemic mixture and resolution of racemic mixtures</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 7 Hours         |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Geometrical isomerism</b> <ul style="list-style-type: none"> <li>Nomenclature of geometrical isomers (Cis &amp; Trans, E &amp; Z, Syn &amp; Anti system)</li> <li>Conformational isomerism and its analysis in ethane, butane and cyclohexane</li> <li>Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity in biphenyl compounds</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 6 Hours  |
| IV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Chemistry of five membered heterocycles</b> <ul style="list-style-type: none"> <li>IUPAC nomenclature and classification of heterocyclic compounds as per the Hansch- Widman system</li> <li>Relative aromaticity and reactivity of pyrrole, furan and thiophene</li> <li>Study of synthesis of pyrrole (Paal – Knorr synthesis), furan (Feist-Bénary reaction), thiophene (Hinsberg synthesis) and Mechanism of Electrophilic substitution reactions of pyrrole, furan and thiophene</li> <li>Medicinal uses of drugs containing pyrrole (Ethosuximide, procyclidine), furan (Furosemide, Nitrofurazone) and thiophene (Cephaloridine, Clopidogrel)</li> </ul>                                                                                                                                                                                                                                                                                                                                            | 10 Hours |
| V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Chemistry of other heterocycles</b> <ul style="list-style-type: none"> <li>Study of nomenclature of fused heterocyclic compounds, synthesis for pyrazole (Knorr synthesis), imidazole (Debus-Radziszewski reaction), pyridine (The Hantzsch synthesis), quinoline (The Skraup synthesis) and Electrophilic aromatic substitution reactions of pyrazole and imidazole</li> <li>Chemical structures of Indole, pyrimidine, benzimidazole, purine, azepine, pyrazole, oxazole, Phenothiazine, benzotriazole, quinoxaline</li> <li>Basicity of imidazole, pyridine and quinoline</li> <li>Medicinal uses of any two drugs containing pyrazole (Sildenafil, Celecoxib), imidazole (Metronidazole, Pilocarpine), pyridine (Isoniazid, Chlorpheniramine), quinoline (Chloroquine, Ciprofloxacin), indole (Indomethacin, Reserpine), benzimidazole (Albendazole, Mebendazole) pyrimidine (Fluorouracil, Sulphadiazine), purine (Mercaptopurine, Thioguanine), azepine (Diazepam, Loxapine) heterocycles</li> </ul> | 07 Hours |
| <b>Recommended References (Preferably latest editions):</b> <ol style="list-style-type: none"> <li>Finar, I. L. <i>Organic Chemistry, Vol. 1</i>. Pearson Education.</li> <li>Finar, I. L. <i>Organic Chemistry: Stereochemistry and Natural Products, Vol. 2</i>. Pearson Education.</li> <li>Smith, M. B. and March, J. <i>March's Advanced Organic Chemistry: Reactions, Mechanisms and Structure</i>. Wiley.</li> <li>Bahl, B. S. and Bahl, A. <i>Textbook of Organic Chemistry</i>. S. Chand.</li> <li>Nadendla, R. R. <i>Pharmaceutical Organic Chemistry: Heterocyclic and Natural Products</i>. Vallabh Prakashan.</li> <li>Gilchrist, T. L. <i>Heterocyclic Chemistry</i>. Prentice Hall.</li> <li>Eliel, E. L. and Wilen, S. H. <i>Stereochemistry of Organic Compounds</i>. Wiley.</li> </ol> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |          |

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| Course Code   | Course Title                                  |    |    | Course Type |
|---------------|-----------------------------------------------|----|----|-------------|
| BP306T        | <b>Pharmaceutical Dosage Forms I (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                        |    |    | Max. Hours. |
|               | L                                             | T  | P  |             |
| 3             | 3                                             | -- | -- | 45          |
| Maximum Marks | SE                                            |    |    | ESE         |
| 75            | 30                                            |    |    | 45          |

## COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamentals of dosage form development, including pre-formulation studies, drug–excipient compatibility, and stability considerations as per ICH guidelines.
2. Acquire knowledge of formulation and manufacturing of compressed solid dosage forms, including tablets and coated tablets, along with quality control and packaging.
3. Develop competence in the formulation and evaluation of finely divided and filled solid dosage forms, such as powders, granules, and hard and soft gelatin capsules.
4. Understand the principles and formulation strategies of modified-release solid dosage forms, including sustained-release and controlled-release systems.
5. Gain knowledge of microencapsulation techniques, their applications, advantages, limitations, and evaluation of microcapsules in pharmaceutical products.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to:                                                                                                                                                  |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Describe pre-formulation principles and evaluate key physicochemical parameters critical to solid dosage-form development.                                                                                                |
| 2      | Apply formulation and manufacturing processes and perform quality control tests for tablets, including coated tablets, and troubleshoot common formulation and processing defects.                                        |
| 3      | Formulate and evaluate finely divided and filled solid dosage forms such as medicated powders, granules, hard capsules, and soft gelatin capsules using appropriate materials, equipment, and quality control procedures. |
| 4      | Design and evaluate modified-release solid dosage forms by selecting suitable polymers and mechanisms to achieve sustained and controlled drug release.                                                                   |
| 5      | Analyze various microencapsulation methods, select suitable techniques for specific drug-delivery needs, and evaluate microcapsules based on physicochemical and performance parameters.                                  |

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## Detailed Syllabus:

| Unit No. | Topics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | No. of Lectures |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <b>Fundamentals of Dosage Form Development:</b><br>Pre-formulation studies: concept, need, and parameters including solubility, pKa, physical nature (amorphous and crystalline), polymorphism, particle size and shape, and powder flow parameters.<br>Drug-excipient compatibility studies.<br>Packaging selection for various dosage forms.<br>Drug product and container-closure interaction.<br>Introduction to stability guidelines of new drug substances and products (ICH Q1).                                                                                                                                   | 07 Hours        |
| II       | <b>Compressed Solids:</b><br><b>Tablets</b><br>Excipients (roles and examples); tooling (types and specifications); manufacturing methods and equipment; tablet defects and remedies; in-process quality control (IPQC); finished-product tests; packaging.<br><b>Tablet Coating</b><br>Types of coating (sugar, film, compression, enteric); need, advantages, and limitations; polymers, process specifications, and equipment; coating defects; quality control of coated tablets.                                                                                                                                     | 12 Hours        |
| III      | <b>Finely Divided and Filled Solids:</b><br>Medicated powders and granules: formulation considerations, manufacturing processes (mixing, granulation), quality control, and packaging.<br>Gelatin and non-gelatin shells: composition, empty shell manufacturing, quality control, and capsule sizes.<br>Hard gelatin capsules: formulation design; filling methods (manual, semi-automatic, automatic); IPQC and finished-product tests; packaging.<br>Soft gelatin capsules: shell composition and plasticizers; fill materials; manufacturing methods (rotary die and others); defects; quality control and stability. | 12 Hours        |
| IV       | <b>Modified-Release Solids:</b><br>Types of tablets: sustained-release and controlled-release tablets.<br>Concept, need, advantages, and disadvantages.<br>Formulation design and drug-release mechanisms.<br>Polymers used for sustained and controlled release.<br>Evaluation of modified-release dosage forms.                                                                                                                                                                                                                                                                                                         | 07 Hours        |
| V        | <b>Microencapsulation:</b><br>Concept, need, advantages, and disadvantages.<br>Methods of microencapsulation: spray drying, spray congealing, extrusion and spheronisation, fluidized bed coating, and phase-separation coacervation.<br>Evaluation of microcapsules.                                                                                                                                                                                                                                                                                                                                                     | 07 Hours        |

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**Recommended References (Preferably latest editions):**

1. Allen, L. V., Popovich, N. G. and Ansel, H. C. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. Lippincott Williams & Wilkins.
2. Aulton, M. E. and Taylor, K. M. G. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. Elsevier.
3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy*. CBS Publishers & Distributors.
4. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy*. Pharmaceutical Press.
5. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications*. CRC Press.
6. Sinko, P. J. *Martin's Physical Pharmacy and Pharmaceutical Sciences*. Lippincott Williams & Wilkins.
7. *Indian Pharmacopoeia*. Indian Pharmacopoeia Commission.
8. *United States Pharmacopeia*. United States Pharmacopeial Convention.
9. *British Pharmacopoeia*. British Pharmacopoeia Commission.



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| Course Code   | Course Title                               |    |    | Course Type |
|---------------|--------------------------------------------|----|----|-------------|
| BP307T        | <b>Pharmaceutical Engineering (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                     |    |    | Max. Hours. |
|               | L                                          | T  | P  |             |
| 3             | 3                                          | -- | -- | 45          |
| Maximum Marks | SE                                         |    |    | ESE         |
| 75            | 30                                         |    |    | 45          |

## COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide fundamental knowledge of pharmaceutical engineering principles and common unit operations involved in solid and liquid pharmaceutical manufacturing.
2. Develop an understanding of thermal operations such as drying, evaporation, distillation, and heat transfer used in pharmaceutical processing.
3. Introduce material handling systems, corrosion control, and waste management practices relevant to pharmaceutical plants.
4. Explain the principles of fluid flow and flow measurement used in pharmaceutical process equipment.
5. Develop knowledge of the design, construction, working principles, and pharmaceutical applications of engineering equipment used in the pharmaceutical industry.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to:                                                                           |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Explain the principles and pharmaceutical applications of unit operations such as size reduction, mixing, size separation, and fluid flow.         |
| 2      | Identify and describe the construction, working, and utility of various pharmaceutical engineering equipment.                                      |
| 3      | Compare and evaluate different thermal processes such as drying, evaporation, distillation, and heat transfer based on operational efficiency.     |
| 4      | Apply principles of safe and efficient material handling and understand the impact of corrosion and waste management in pharmaceutical industries. |
| 5      | Examine the relevance of contemporary technological trends such as PAT and automation for enhancing pharmaceutical manufacturing processes.        |

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## Detailed Syllabus:

| Unit No. | Topics                                                                                                                                                                                                                                                                                                                                                      | No. of Lectures |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <b>Unit operations associated with solids</b><br>Principle, construction, working, advantages and disadvantages and Pharmaceutical applications of size reduction, size separation and mixing equipment                                                                                                                                                     | 12 Hours        |
| II       | <b>Unit operations associated with liquids</b><br>Principle, construction, working, advantages and disadvantages and Pharmaceutical applications of filtration, crystallization and centrifugation equipment                                                                                                                                                | 12 Hours        |
| III      | <b>Unit operations associated with heat transfer</b><br>Principle, construction, working, advantages and disadvantages and Pharmaceutical applications of evaporation, drying, distillation and Heat transfer equipment                                                                                                                                     | 12 Hours        |
| IV       | <b>Materials and material handling</b><br>Introduction to material handling equipment and techniques, Conveyors, hoists, and automated guided vehicles (AGVs), Storage systems: bins, silos in warehouses, Safety considerations in material handling and waste management. Types of corrosion and their impact on pharmaceutical processes and environment | 05 Hours        |
| V        | <b>Flow of fluids</b><br>Types and measurement of flow, manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Orifice meter, Venturimeter, Pitot tube and Rotometer.                                                                                                                                                  | 04 Hours        |

### Recommended References (Preferably latest editions):

1. Banker, G. S. *Pharmaceutical Engineering*. Marcel Dekker.
2. Sambamurthy, K. *Introduction to Pharmaceutical Engineering*. New Age International.
3. Kennedy, T. F. *Good Design Practices for GMP Pharmaceutical Facilities*. CRC Press.
4. Banker, G. S. and Rhodes, C. T. *Modern Pharmaceutics*. CRC Press.
5. Hickey, A. J. *Pharmaceutical Process Engineering*. CRC Press.
6. Cole, G. C. *Pharmaceutical Facilities: Design, Layouts and Validation*. CRC Press.
7. Bertch, F. J. *Fundamentals of Modern Pharmaceutical Process Engineering*. Academic Press.
8. Chase, A. G. *Environmental Management in the Pharmaceutical Industry*. Springer.
9. Bunn, G. *Pharmaceutical Production Facilities: Design and Applications*. CRC Press.

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| Course Code   | Course Title                                |    |    | Course Type |
|---------------|---------------------------------------------|----|----|-------------|
| BP308T        | <b>Pharmaceutical Microbiology (Theory)</b> |    |    | Core        |
| Credit        | Hours Per Week (L-T-P)                      |    |    | Max. Hours. |
|               | L                                           | T  | P  |             |
| 3             | 3                                           | -- | -- | 45          |
| Maximum Marks |                                             | SE |    | ESE         |
| 75            |                                             | 30 |    | 45          |

## COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts of microbiology and its relevance to pharmaceutical sciences.
2. Provide insights into the industrial application of microorganisms in the manufacture of pharmaceutical products.
3. Provide knowledge Good Manufacturing Practices (GMP) related to microbial contamination control.
4. Provide understanding in microbial evaluation techniques such as sterility testing, microbial limit tests, and microbial assay.
5. Familiarize students with sterilization technologies, microbial spoilage control, and in vitro cell culture techniques for pharmaceutical research and quality assurance.

## COURSE OUTCOMES (CO):

| CO No. | Upon successful completion of this course, the students will be able to:                                                                                                                    |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Explain the basic concepts of microbiology and the role of microorganisms in pharmaceuticals.                                                                                               |
| 2      | Identify and differentiate microorganisms using staining and biochemical techniques.                                                                                                        |
| 3      | Evaluate microbial contamination sources and apply GMP-based strategies for contamination control.                                                                                          |
| 4      | Describe microbial spoilage mechanisms and select appropriate disinfectants, antiseptics, or preservatives.                                                                                 |
| 5      | Compare various sterilization methods and assess their effectiveness and validation parameters and perform microbial limit and sterility tests in compliance with pharmacopeial guidelines. |

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## Detailed Syllabus:

| Unit No. | Topics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | No. of Lectures |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| I        | <b>Introduction and role of microorganisms in pharmaceutical industry</b> <ul style="list-style-type: none"> <li>Fundamentals of microbiology: Microorganisms and medicines, Introduction to various microorganisms, Microbial cultivation, isolation and enumeration. Pharmaceutical importance of microorganisms.</li> <li>Introduction to Microscope (Compound and Electron Microscope)</li> <li>Identification of bacteria using staining techniques (simple, Gram's &amp; Acid-fast staining) and biochemical tests (IMViC).</li> <li>Antibiotics produced by microbiology (Production and uses streptomycin, cephalosporin)</li> </ul> | 09 Hours        |
| II       | <b>Evaluation of microbiological contamination</b> <ul style="list-style-type: none"> <li>Sources and types of microbial contaminant</li> <li>Control of microbial contamination during manufacture of Nonsterile dosage forms and sterile dosage forms (including Aseptic area), control of Atmosphere, Water, Raw material, Facility, Packaging, Equipment</li> <li>Microbiological spoilage of pharmaceuticals, Factors affecting microbial spoilage of pharmaceuticals.</li> <li>Introduction to Fermentation, types and fermenters.</li> </ul>                                                                                          | 09 Hours        |
| III      | <b>Microbial control and evaluation</b><br>Designing of aseptic area. Laminar flow equipment's, clean area classification, Biological Safety Level categories. Methods of prevention. Disinfectants, antiseptics, and preservatives, and their evaluation, Factors affecting the antimicrobial activity of disinfectants                                                                                                                                                                                                                                                                                                                     | 09 Hours        |
| IV       | <b>Sterilization procedures, assurance and evaluation</b> <ul style="list-style-type: none"> <li>Physical, chemical, gaseous, radiation and mechanical methods of sterilization, Advances sterilization technologies, Evaluation of efficiency of sterilization; Validation of sterilization procedures and Sterility indicators.</li> <li>Sterility assurance, Bioburden determination, Modelling in predicting microbial growth and death, Test for bacteriostatic, bactericidal activity</li> </ul>                                                                                                                                       | 09 Hours        |
| V        | <b>Microbiological quality control</b> <ul style="list-style-type: none"> <li>Microbial limit tests and Microbial assay (antibiotics, vitamins and amino acids)</li> <li>Sterility testing of products according to IP, BP and USP</li> <li>Methods for monitoring Water and Air Quality</li> </ul> In vitro cell cultures, general procedure for cell culture, Application                                                                                                                                                                                                                                                                  | 09 Hours        |

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | of cell cultures in pharmaceutical industry and research |  |
| <p><b>Recommended References (Preferably latest editions):</b></p> <ol style="list-style-type: none"> <li>1. Pelczar, M. J., Chan, E. C. S. and Krieg, N. R. <i>Microbiology: Concepts and Applications</i>. McGraw-Hill.</li> <li>2. Prescott, L. M., Harley, J. P. and Klein, D. A. <i>Microbiology</i>. McGraw-Hill.</li> <li>3. Hugo, W. B. and Russell, A. D. <i>Pharmaceutical Microbiology</i>. Blackwell Science.</li> <li>4. Waites, M. J., Morgan, N. L., Rockey, J. S. and Higton, G. <i>Industrial Microbiology: An Introduction</i>. Blackwell Science.</li> <li>5. Denyer, S. P., Hodges, N. A. and Gorman, S. P. <i>Hugo and Russell's Pharmaceutical Microbiology</i>. Wiley-Blackwell.</li> <li>6. Atlas, R. M. <i>Handbook of Microbiological Media</i>. CRC Press.</li> <li>7. Sandle, T. <i>Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control</i>. Elsevier.</li> <li>8. Sutton, S. V. W. <i>Microbiology in Pharmaceutical Manufacturing</i>. PDA/DHI Publishing.</li> </ol> |                                                          |  |