



**Dr. Rafiq Zakaria Campus**  
Maulana Azad Educational Trust's

**Y. B. CHAVAN COLLEGE OF PHARMACY**

(B. Pharm, M. Pharm & Research Centre)

ISO 21001:2018 & ISO 14001:2015 CERTIFIED | NIRF-2022 ALL INDIA RANK 65<sup>TH</sup>

**NAAC ACCREDITATION "A" GRADE WITH 3.23 CGPA SCORE**

# COURSE MODULE

|                      |                                                |
|----------------------|------------------------------------------------|
| <b>Program Title</b> | M. Pharmacy                                    |
| <b>Department</b>    | Pharmaceutical Chemistry                       |
| <b>Course Title</b>  | Pharmaceutical Process Chemistry<br>(MPC 204T) |

1. **NAME OF INSTITUTION** : Y. B. CHAVAN COLLEGE OF PHARMACY,  
AURANGABAD
2. **AFFILIATED UNIVERSITY** : DR. BABASAHEB AMBEDKAR  
MARATHWADA UNIVERSITY, AURANGABAD
3. **DEPARTMENT** : PHARMACEUTICAL CHEMISTRY
4. **PROGRAM TITLE** : M. PHARM.

**4.1. Program Specific Outcome: After completing the program, student will be able to:**

PSO-1: Highlight advancements in knowledge associated with medicinal chemistry, Natural products chemistry, drug discovery, drug design and analytical techniques.

PSO-2: Independently carry out the design of bioactive molecules and synthetic research work.

PSO-3: Interpret the spectra of synthetic compounds, natural products and determine their structures.

PSO-4: Build professional, computational, analytical and critical thinking skills

PSO-5: Explain the unit operation and unit reactions in process chemistry

## 5. COURSE SPECIFICATION :

### 5.1.Course Identification and General Information

|                                                         |                                                         |           |
|---------------------------------------------------------|---------------------------------------------------------|-----------|
| a. Course Title:                                        | <b>Pharmaceutical Process Chemistry</b>                 |           |
| b. Course Number/Code                                   | <b>MPC 204T</b>                                         |           |
| c. Credit Hours                                         | Theory                                                  | Practical |
|                                                         | <b>60(4hr/wk)</b>                                       | <b>00</b> |
| d. Study level/semester at which this course is offered | <b>Second Semester M. Pharm.</b>                        |           |
| e. Pre-requisite                                        | <b>Unit process and unit operation</b>                  |           |
| f. Co-requisite                                         | Common organic reaction and industrial scale up process |           |
| g. Program in which the course is offered               | M. Pharm                                                |           |
| h. Language of teaching the course                      | English                                                 |           |
| i. Prepared by                                          | <b>Dr. Mirza Shahed Baig<br/>(M. Pharm IInd SEM)</b>    |           |
| j. Approved by HOD                                      | <b>Dr. K. G. Baheti</b>                                 |           |

### 5.2. Course Description:

The course is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

### 5.3. Course Objectives:

- The strategies of scale up process of API and intermediates
- The various unit operations and various reactions in process chemistry

### 6.0. Course Outcomes (COs) : (Min. 4 and Max. 6)

(Use Bloom's Taxonomy words)

After completion of course, the student should be able to

| CO Code   | Course outcome                                                                                   |
|-----------|--------------------------------------------------------------------------------------------------|
| CO 204.01 | Differentiate between unit operation and unit process of API industry                            |
| CO 204.02 | Design the synthetic routes for organic compounds involving unit process reaction                |
| CO 204.03 | Explain the strategies of scale up process of API's & intermediates including impurities in API. |
| CO 204.04 | Understand industrial safety measure, possible hazards, health and safety assessments.           |

### 6.1. Knowledge and Understanding

(Alignment of PSOs to COs)

| Course outcome<br>Code | Program Specific Outcome |       |       |       |       |
|------------------------|--------------------------|-------|-------|-------|-------|
|                        | PSO-1                    | PSO-2 | PSO-3 | PSO-4 | PSO-5 |
| CO 204.01              | H                        | -     | -     | M     | -     |
| CO 204.02              | M                        | H     | -     | M     | H     |
| CO 204.03              | M                        | H     | -     | -     | H     |
| CO 204.04              | H                        | H     | -     | H     |       |

Correlation levels 1, 2 or 3 as defined below:

1: Slight (Low); 2: Moderate (Medium); 3: Substantial High); If there is no correlation, put '-'

## 6.2. Teaching and Assessment Methods for achieving learning outcome:

| Teaching Strategies(methods)/Tools used                                                                                                                                                                                                               | Methods of Assessment                                                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Lectures (Constructivist learning)</b><br><b>Collaborative learning (Discussion)</b><br><b>Project based Learning</b><br><b>Blended learning</b><br><b>Inquiry based learning</b><br><b>Flash cards</b><br><b>Video</b><br><b>Equipment models</b> | <b>Formative Assessment</b><br><b>Case study</b><br><b>Class test</b><br><b>Multiple choice questions</b><br><b>Assignments</b><br><b>Seminar</b><br><b>Viva Voce</b><br><b>Synopsis</b><br><b>Tutorials</b><br><b>Summative Assessment</b> |

## 6.3. Tools for the Teaching and learning

| Theory subjects                                                                                                                                                                                                                                                                                              | Practical Subjects                                                                                                                                                                                                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• <b>PowerPoints presentation</b></li><li>• <b>Videos</b></li><li>• <b>Flash Card</b></li><li>• <b>Models</b></li><li>• <b>Software</b></li><li>• <b>Charts</b></li><li>• <b>Smart Boards</b></li><li>• <b>White boards</b></li><li>• <b>Online Platform</b></li></ul> | <ul style="list-style-type: none"><li>• <b>White boards</b></li><li>• <b>Glassware</b></li><li>• <b>Chemicals</b></li><li>• <b>Instruments</b></li><li>• <b>Equipment</b></li><li>• <b>Software</b></li><li>• <b>Models</b></li><li>• <b>Plants/Crude Drugs</b></li><li>• <b>Animal</b></li></ul> |

## 6.4. COURSE CONTENT

### 6.1. Theoretical Aspect:

| Order | Topic list/units                      | Subtopics list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Number of Weeks | Contact Hours |
|-------|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------|
| 1     | <b>Unit-I:</b><br>Process chemistry   | Introduction, Synthetic strategy<br>Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including Genotoxic impurities                                                                                                                                                                                                                                                                                    | 03              | 12 Hrs        |
| 2     | <b>UNIT-II</b><br>Unit operations     | a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.<br>b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,<br>c) Distillation: azeotropic and steam distillation<br>d) Evaporation: Types of evaporators, factors affecting evaporation.<br>e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, Nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs. | 03              | 12 Hrs        |
| 3     | <b>UNIT-III</b><br>Unit Processes - I | a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,<br>b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.<br>c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H <sub>2</sub> O <sub>2</sub> , sodium hypochlorite,                                                  | 03              | 12 Hrs        |

|   |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |           |               |
|---|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------|
|   |                                       | Oxygen gas, ozonolysis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |           |               |
| 4 | <b>UNIT-IV</b><br>Unit Processes - II | a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.<br>b) Fermentation: Aerobic and anaerobic fermentation. Production of<br>i. Antibiotics; Penicillin and Streptomycin,<br>ii. Vitamins: B2 and B12<br>iii. Statins: Lovastatin, Simvastatin<br>c) Reaction progress kinetic analysis<br>i. Streamlining reaction steps, route selection,<br>ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up. | <b>03</b> | <b>12 Hrs</b> |
| 5 | <b>UNIT-V</b><br>Industrial Safety    | a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)<br>b) Fire hazards, types of fire & fire extinguishers<br>c) Occupational Health & Safety Assessment Series 1800(OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management                                                                                                                                                                                                                                                                                                 | <b>03</b> | <b>12 Hrs</b> |
|   | <b>TOTAL</b>                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |           | <b>60 Hrs</b> |

## 6.2. Practical Aspects

| Order | Name of Experiment | Number of Weeks |
|-------|--------------------|-----------------|
|       |                    |                 |

## 7.0. ASSESSMENT MECHANISM:

| Sr. No. | Assessment Mechanism                                       | Week due                            | Marks | Proportion of Final Assessment |
|---------|------------------------------------------------------------|-------------------------------------|-------|--------------------------------|
| 1       | Continuous Assessment (Theory)                             | 2 <sup>nd</sup> week of every month | 10    | 4%                             |
| 2       | Sessional (Internal Theory exam)                           | As per schedule of examination      | 15    | 6%                             |
| 3       | Continuous Practical Assessment (Sessional Practical exam) | Weekly during practical             | 20    | 8%                             |
| 4       | Sessional (Internal Practical exam)                        | As per schedule of examination      | 30    | 12%                            |
| 5       | Final exam (theory)                                        | As per University at end of course  | 75    | 30%                            |
| 6       | Final exam(practical)                                      |                                     | 100   | 40%                            |
| Total   |                                                            |                                     | 150   | <b>100%</b>                    |

#### 8.0.STUDENT SUPPORT:

| Office hours/week        | Other procedures             |
|--------------------------|------------------------------|
| <b>Two hours minimum</b> | <b>MENTORING AND GUIDING</b> |

#### 9.0.TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

| Days | Monday           | Tuesday          | Wednesday        | Thursday         | Friday           | Saturday         |
|------|------------------|------------------|------------------|------------------|------------------|------------------|
| Time | <b>4:00-5:00</b> | <b>4:00-5:00</b> | <b>4:00-5:00</b> | <b>4:00-5:00</b> | <b>4:00-5:00</b> | <b>4:00-5:00</b> |

#### 10.0. LEARNING RESOURCES:

| Sr. No. | Title of Learning Material | Details                                                                                                                                                                                                                                                                                                                                                                                    |
|---------|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1       | Text books                 | 1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.<br>2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.<br>3. Medicinal Chemistry by Burger, 6 th edition, Volume 1-8.<br>4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill |

|   |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   |                          | <p>5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)</p> <p>6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis</p> <p>7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up</p> <p>8. P.H.Groggins: Unit processes in organic synthesis (MGH)</p> <p>9. F.A.Henglein: Chemical Technology (Pergamon)</p> <p>10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-WestPress</p> <p>11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,</p> <p>12. Lowenheim &amp; M.K. Moran: Industrial Chemicals</p> <p>13. S.D. Shukla &amp; G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House</p> <p>14. J.K. Stille: Industrial Organic Chemistry (PH)</p> <p>15. Shreve: Chemical Process, Mc Grawhill.</p> <p>16. B.K.Sharma: Industrial Chemistry, Goel Publishing House</p> <p>17. ICH Guidelines</p> <p>18. United States Food and Drug Administration official website <a href="http://www.fda.gov">www.fda.gov</a></p> |
| 2 | Reference material       | <p>1) P.H.Groggins: Unit processes in organic synthesis (MGH)</p> <p>2. C.V.S. Subrahmanyam -Pharmaceutical Engineering Unit Operations Principles And Practice Vallabh Prakashan, 2002</p> <p>3. United States Food and Drug Administration official website <a href="http://www.fda.gov">www.fda.gov</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3 | E-materials and websites | PPT's, Text Notes, Soft copies (word/Pdf files)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4 | Other learning material  | College WhatsApp Group                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

#### 11.0. FACILITIES REQUIRED:

| Sr. No. | Particular of Facility Required |
|---------|---------------------------------|
|---------|---------------------------------|

|   |                                                                                                                                    |
|---|------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Lecture Rooms (capacity for 60 students)                                                                                           |
| 2 | Laboratory (capacity for 20 students)                                                                                              |
| 3 | Computing resources: PC with latest version and hardware/software and utilization of open source and licensed application software |
| 4 | Other resources: Appropriate laboratory tools, Chemicals, Glass ware, Apparatus, Instrumentation                                   |

## **12.0. COURSE IMPROVEMENT PROCESSES:**

### **12.1. Strategies for obtaining student feedback on effectiveness of teaching:**

Course delivery evaluation by students using: Questionnaire forms and online questionnaires

### **12.2. Other strategies for evaluation of teaching by the instructor or by the department:**

Periodic review by Academic Planning & Monitoring Committee and departmental review committee, Observations and assistance of colleagues, External assessments by advisors/ examiners and auditors.

### **12.3. Process for improvement of teaching:**

Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

### **12.4. Describe the planning procedures for periodically reviewing of course effectiveness and planning for improvement:**

Periodic review by departmental meeting, Review of course delivery and outcome through assessment and feedback from all stake holders.

### **12.5. Course development plans:**

Provide inputs for course improvement and update to University Course development Committees (Board of Studies)

## **13.0. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:**

|                                               |                                                     |
|-----------------------------------------------|-----------------------------------------------------|
| <b>Name</b>                                   | <b>Dr. Mirza Shahed Baig (MSB)</b>                  |
| <b>Location</b>                               | <b>Department of Pharmaceutical Chemistry</b>       |
| <b>Contact Detail (e-mail &amp; cell no.)</b> | <b>mirzashahedbaig@ybcca.ac.in &amp; 9890336238</b> |
| <b>Office Hours</b>                           | <b>10:00 AM to 5:00 PM</b>                          |

