



**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**

<b>Program Title</b>	B. Pharmacy
<b>Department</b>	Pharmaceutics
<b>Course Title</b>	Pharmaceutical Jurisprudence

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

**4.1. Program Outcomes(PO):**

- PO 01: Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
- PO 02: Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
- PO 03: Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
- PO 04: Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
- PO 05: Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.
- PO 06: Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
- PO 07: Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
- PO 08: Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
- PO 09: The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

**PO 10: Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

**PO 11: Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## 5. COURSE SPECIFICATION :

### 5.1. Course Identification and General Information

a. Course Title:	Pharmaceutical Jurisprudence (Theory)		
b. Course Number/ Code	BP505T		
c. Credit Hours	Theory	Practical	Total
	45	—	45
d. Study level/ semester at which this course is offered	SEMESTER		
e. Pre-requisite	Basic concepts and knowledge about the various regulatory bodies		
f. Co-requisite	Definitions ,Applications, Rules, regulation and provisions Offences & Penalties		
g. Language of teaching the course	English		
h. Prepared by	Mr. Shaikh Shoaib , Shaikh Sabina Meraj		
i. Approved by	Dr S R Lahoti.		

### 5.2. Course Description:

Enforced to control and regulate drugs, pharmaceuticals, cosmetics and allied substance and pharmacy profession. Code of moral principles while dealing with patients, public, fellow pharmacist and members of medical profession. Form and manner of application for licensed, registration certificate. Knowledge of education regulation programmed. Knowledge about PCI and the standards set for education regulation practice of pharmacist. Restriction and condition to be satisfied for licensed

### 5.3. Course Objectives:

- The subject exposes the student to important legislations related to Pharmacy profession in India
- It imparts knowledge about the Drug and Cosmetic Act and its Rules.
- It provides the basic idea regarding DPCO drug policies and patenting in India.

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

Code	Course outcome
<b>CO. BP505T.01</b>	Describe the significance and relevance of Pharmaceutical laws in India and role of Ethics in pharmacy profession while dealing with patients, public, fellow pharmacist and members of medical profession
<b>CO. BP505T.02</b>	Ability to know various schedules and their applications in pharmacy as well as laws and penalties.
<b>CO. BP505T.03</b>	Ability to apply and knowledge of various drug licenses, registration certificate, cancellation of licenses
<b>CO. BP505T.04</b>	Describe the Patent, process, advantage, essential documents with patent application amendments to Indian patent act
<b>CO. BP505T. 05</b>	Explain the role of various Regulatory bodies like Advisory, analytical, executive bodies

### 6.1. Knowledge and Understanding

#### (Alignment of POs to COs)

Course code (CO)											
	PO 1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
<b>CO. BP505T.01</b>	M	—	—	—	—	S	H	—	M	—	M
<b>CO. BP505T.02</b>	H	—	—	—	—	M	H	—	M	—	M
<b>CO. BP505T.03</b>	H	—	S	S	—	M	H	—	M	S	H
<b>CO. BP505T.04</b>	H	H	M	M	—	—	H	—	M	—	S
<b>CO. BP505T. 05</b>	M	—	M	—	S	S	H	—	S	—	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> <b>Collaborative learning (Discussion)</b> <b>Project based Learning</b> <b>Blended learning</b> <b>Inquiry based learning</b> <b>Flash cards</b> <b>Video</b> <b>Equipment models</b>	<b>Formative Assessment</b> <b>Case study</b> <b>Class test</b> <b>Multiple choice questions</b> <b>Assignments</b> <b>Seminar</b> <b>Viva Voce</b> <b>Synopsis</b> <b>Tutorials</b> <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. COURSECONTENTS:

### 6.1. TheoreticalAspect:

Order	Topic list/units	Subtopics list	Hrs
1	<b>UNIT-I</b>	<b>Drugs and Cosmetics Act, 1940 and its rules 1945:</b> <input type="checkbox"/> Objectives, Definitions, Legal definitions of schedules to the act and rules <input type="checkbox"/> Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. <input type="checkbox"/> Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, <input type="checkbox"/> Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	10
2	<b>UNIT-II</b>	<b>Drugs and Cosmetics Act, 1940 and its rules 1945.</b> <input type="checkbox"/> Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) <input type="checkbox"/> Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties <input type="checkbox"/> Labeling &Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. <input type="checkbox"/> Administration of the act and rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors	10
3	<b>UNIT-III</b>	<b>Pharmacy Act –1948:</b> Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and <b>Medicinal and Toilet Preparation Act –1955:</b> Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties. <input type="checkbox"/> <b>Narcotic Drugs and Psychotropic substances Act-1985 and Rules:</b> Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	10

4	<b>UNIT-IV</b>	<b>Study of Salient Features of Drugs and magic remedies Act and its rules:</b> Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties <input type="checkbox"/> <b>Prevention of Cruelty to animals Act-1960:</b> Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties <input type="checkbox"/> <b>National Pharmaceutical Pricing Authority:</b> Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)	08
5	<b>UNIT-V</b>	<b>Pharmaceutical Legislations –</b> A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee <input type="checkbox"/> <b>Code of Pharmaceutical ethics</b> Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath <input type="checkbox"/> <b>Medical Termination of pregnancy act</b> <input type="checkbox"/> Right to information Act <input type="checkbox"/> Introduction to Intellectual Property Rights (IPR)	07

## 7.0.ASSESSMENT MECHANISM :

Sr. No.	Assessment Mechanism	Week due	Marks	Proportion of Final Assessment
1	Assignments, Exercises & Home works	2 <sup>nd</sup> week of every month	10	6%
2	Sessional (Internal Theory exam)	As per scheduled examination	15	10%
3	Final exam (theory)	As per University at end of course	75	50%

Total		As per University at end of course	100	<b>100%</b>
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### 8.0.STUDENT SUPPORT:

Office hours/week	Other procedures
<b>Two hours minimum</b>	

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

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	<b>10:00 am-5:00 pm</b>	<b>10:00 am-5:00 pm</b>	<b>10:00 am-5:00 pm</b>	<b>10:00 am-5:00 pm</b>	<b>10:00 am-5:00 pm</b>	<b>10:00 am-5:00 pm</b>

Sr. No.	Title of Learning Material	Details
01	Text books	<ul style="list-style-type: none"> <li>Relevant Acts (Bare acts) and Rules Published, Govt. of India.</li> <li>Dr. B. S. Kuchekar. Pharmaceutical Jurisprudence Niraliprakashan.</li> <li>Singh Harkishan, History of Pharmacy in India, vol-I, II, &amp; III, Vallabh Prakashan, Delhi</li> <li>S.W. Deshpande, Drug and Cosmetics Act., CBS Publications</li> </ul>
02	Essential references (as per syllabus)	<ul style="list-style-type: none"> <li>Mittal B.M., Test Book of Forensic Pharmacy Vallabh Prakashan, New Delhi</li> <li>NK Jain, Forensic Pharmacy, Vallabh Prakashan, New Delhi</li> </ul>
03	E-materials and websites	<a href="http://www.bookganga.com/R/4PPT8">http://www.bookganga.com/R/4PPT8</a>
04	Other learning material	Question papers, charts. Printed and Handwritten notes



#### **10.0.LEARNINGRESOURCES:**

#### **11.0.FACILITIES REQUIRED:**

r. 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. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:**

<b>Name</b>	Mr. SHAIKH SHOAIB
<b>Location</b>	Pharmaceutics lab
<b>Contact Detail (e-mail &amp;cell no.)</b>	9665332321
<b>Office Hours</b>	10:00 AM to 5:00 PM

<b>Name</b>	Ms. Shaikh Sabina Meraaj
<b>Location</b>	Exam Unit
<b>Contact Detail (e-mail &amp; Cell No.)</b>	9923087700
<b>Office Hours</b>	10:00 AM to 5:00 PM