B. PHARMACY
Syllabus • Semester-8

Elective subject-2 name with code: 13PH0804 Pharmaceutical Regulatory Science

Course Objective
This course is designed to impart fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like the US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Course Outcomes
Upon completion of the course, the student shall be able to
1. Know about the process of drug discovery and development.
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
3. Know the regulatory approval process and their registration in Indian and international markets.

Teaching and assessment scheme

<table>
<thead>
<tr>
<th>Teaching Scheme (Hours)</th>
<th>Theory</th>
<th>Tutorial</th>
<th>Practical</th>
<th>Credits</th>
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<tr>
<td>CSE</td>
<td>10</td>
<td>15</td>
<td>75</td>
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<td>Total Marks</td>
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Theory syllabus

Unit-1
New drug discovery and development: Stages of drug discovery, drug development process, pre-clinical studies, nonclinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit-2
Regulatory approval process: Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Changes to an Approved NDA/ANDA. Regulatory authorities and agencies: Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).

Unit-3

Unit-4

Unit-5

Tutorials will be based on the above syllabus.

Teaching hours: 15 Hours

Recommended references (Latest edition)
1. Drug Regulatory Affairs by Sachin Itkar, Dr N. S. Vyawahare, Nirali Prakashan.