

Course Type	Course Code	Name of Course	L	T	P	Credit
DE	NCYD541	Pharmaceutical Management	3	0	0	3

Course Objective
<ul style="list-style-type: none"> <li>This course enables the students to get understanding of pharma sector from managerial perspective</li> </ul>
Learning Outcomes
<ul style="list-style-type: none"> <li>The topics are framed to enhance students' knowledge of quality systems in pharma industry, ICH and GMP requirements, applications of six sigma principles and quality by design with relevant case studies</li> </ul>

Unit No.	Topics to be Covered	Lecture Hours	Learning Outcome
1	<b>Pharma business environment:</b> Evolution of pharma sector; legal and regulatory requirement, R&D in pharmaceutical industry, Six Sigma and its approach to drug discovery .	8L	Overview of pharma sector; evolution of pharma sector, regulatory requirements
2	<b>Pharmaceutical quality systems:</b> Importance of quality, ISO management systems, basics of quality management, total quality management, McKinsey 7s model, quality by design, WHO-GMP requirements	8L	Guidelines monitoring quality in pharma sector
3	<b>ICH guidelines:</b> stability testing of new drug substances, products and dosage forms, impurities, risk management, quality management for continuous manufacturing of drug substances and products	9L	ICH guidelines for stability and quality
4	<b>Production and operations:</b> facility planning, layout planning, inventory control; product and process layouts, Statistical process control	8L	Various aspects of Planning involved in pharma industry
5	Case studies in pharmaceutical management	9L	Various case studies involved in pharma sector
<b>Total</b>		<b>42</b>	

#### Text Books:

- 1) Pharmaceutical Industrial Management, Shah, 2010

#### Reference Books:

- 1) Concepts of Quality Management in Pharmaceutical Industry, Manohar A. Potdar, 2016.
- 2) Quality Assurance of Pharmaceuticals- A compedium of guide lines and related materials Vol I & II, 2nd edition, WHO Publications