Course Type	Course Code	Name of Course	L	T	P	Credit
DE	NCYD536	Quality Control & Pharmaceutical Analysis	3	0	0	3

Course Objective
• To know the strategies to maintain the quality of drugs in order ensure that each medicine reaching a patient is safe, effective, and of appropriate quality.
Learning Outcomes
• Knowledge about QC & QA and their use in pharmaceutical industry analytical method and their validation.

Unit No.	Topics to be Covered	Lecture Hours	Learning Outcome
1	Good manufacturing practices (GLP) and its applications to pharmaceutical industry. Basic principles and concepts of quality management viz. quality control, quality assurance, quality auditing and ISO system etc. Sampling, finished products labeling, distribution records.	15L	Students will learn basics of manufacturing practices, quality control of pharmaceutical industry.
2	Document control: Issuance, storage and retrieval. Standard operating procedures: Change control procedure and annual product review.	12L	Students will learn about various documentation and operating procedures in pharmaceutical industry.
3	Basic principles of validation: Validation protocols, analytical method validation and process validation. Technology transfer from R & D to manufacturing. Product change over, basic requirements of cleaning and its Validation Market complaint and handling of returned goods.	15L	Students will learn about principles, process and importance of Validation in pharmaceutical industry.
TOTAL		**42**	

Text Books:

1) Good Pharmaceutical Manufacturing Practice: Rationale and Compliance, JohnSharp, CRC Press, 1st Ed. (2004).

Reference Books:

2) Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials by D.H. Shah, Q.A. Manual, World Health Organization, 2nd Ed. (2007).