Scheme Version	Quality Assurance & Quality Control Management	L	T	P	C
		2	0	0	2
VAC 09	**Prerequisite:** -Nil	**Total hours =30**			
	Objectives				
	This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.				
Subject Outcome/Course Outcome					
1	Understand the cGMP aspects in a pharmaceutical industry.				
2	Appreciate the importance of documentation.				
3	Understand the scope of quality certifications applicable to pharmaceutical industries.				
4	Understand the responsibilities of QA & QC departments.				

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10 hours

1. Definition and concept of Quality control
2. Quality assurance and GMP
3. Total Quality Management (TQM) – definition, elements

UNIT-2

10 hours

4. Purpose, participants, process of harmonization
5. Brief overview of QSEM, with special emphasis on Q-series guidelines

6. Quality By Design (QbD) - Definition, overview, elements of QbD program, tools

UNIT-3

10 hours

7. ISO 9000 & ISO 14000 and NABL accreditation
8. Overview, Benefits of ISO 9000 & ISO 14000
9. Elements, steps for registration (ISO 9000 & ISO 14000
10. NABL Accreditation - Principles and procedures

TEXTBOOKS

T-1: Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related materials Vol I WHO Publications.
T-2: A guide to Total Quality Management- KushikMaitra and Sedhan K Ghosh.
T-3 : How to Practice GMP's – P P Sharma.
T-4: ISO 9000 and Total Quality Management – Sadhank G Ghosh.

T-5: The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality sp6cification for Pharmaceutical Substances, Excipients and Dosage form.
T-6: Good laboratory Practices – Marcel Deckker Series.
T-7: ICH guidelines, ISO 9000 and 14000 guidelines.

REFERENCE BOOK

R-1 : Quality Assurance Guide by organization of Pharmaceutical Products of India.

R-2 : Good Laboratory Practice Regulations, Sandy Weinberg Vol. 69.