



**SANDIP**  
UNIVERSITY  
— UGC Recognised —  
Under Section 2(f) & 12(B) of UGC

# School of Pharmaceutical Sciences

Value added course

## Quality Assurance & Quality Control



SEMESTER  
**VI**

COURSE DURATION  
**30 HRS**

AY  
**2025-2026**

### Modules

- › Quality Assurance and Quality Management concepts: 3 hrs. (5 Hrs)
- › ICH Guidelines: 7 hrs
- › Quality by design (QbD): 5 hrs.
- › Calibration and Validation: 12 hrs.
- › Preparation of SOPs- 3 hrs.

### Course objective

- › Understanding Definition and concept of Quality control, Quality assurance and GMP  
Understand the Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines.
- › Understanding Definition, overview, elements of QbD program, tools.
- › To Study about general principles of calibration, qualification and Validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Calibration of Dissolution apparatus, Qualification of UV-Visible spectrophotometer.
- › To Study regarding Preparation of basic SOPs for instrument handling and maintenance.

### Course outcome

- › Student get knowledge about Definition and concept of Quality control, Quality assurance and GMP
- › Students understand overview, elements of QbD program, tools
- › Students understand general principles of calibration, qualification and Validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Calibration of Dissolution apparatus, Qualification of UV-Visible spectrophotometer.
- › Students understand how to prepare basic SOPs for instrument handling and maintenance

**COURSE COORDINATOR**

**DR. RAHUL HAZARE**

**NAME OF DEAN**

**DR. ABHIJEET D KULKARNI**

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