



# Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

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## M.Pharm PHARMACEUTICAL QUALITY ASSURANCE SEMESTER: II

**Subject Name:** PHARMACEUTICAL QUALITY ASSURANCE

**Subject Code:** MQA205P

**Teaching scheme and examination scheme:**

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
0	0	12	6	0	0	100	50

### List of Practicals:

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air
5. Estimation of Chlorine in Work Environment
6. Sampling and analysis of SO<sub>2</sub> using Colorimetric method
7. Qualification of following Pharma equipment
  - A) Autoclave
  - B) Hot air oven
  - C) Powder Mixer (Dry)
  - D) Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of atleast two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production
15. Check list for sterile production area
16. Check list for Water for injection
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT