



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

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard,
Amargadh – Bhichari, Raikot. Mo. 9099063150. 9727753360

M.Pharm PHARMACEUTICAL QUALITY ASSURANCE SEMESTER: I

Subject Name: PHARMACEUTICAL QUALITY ASSURANCE

Subject Code: MQA105P

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:

PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

1. Case studies on
 - a. Total Quality Management
 - b. Six Sigma
 - c. Change Management/ Change control. Deviations,
 - d. Out of Specifications (OOS)
 - e. Out of Trend (OOT)
 - f. Corrective & Preventive Actions (CAPA)
 - g. Deviations
2. Development of Stability study protocol
3. Estimation of process capability
4. In process and finished product quality control tests for tablets, capsules,
5. parenterals and semisolid dosage forms.
6. Assay of raw materials as per official monographs
7. Testing of related and foreign substances in drugs and raw materials
8. To carry out pre formulation study for tablets, parenterals (2 experiment).
9. To study the effect of pH on the solubility of drugs, (1 experiment)
10. Quality control tests for Primary and secondary packaging materials
11. Accelerated stability studies (1 experiment)
12. Improved solubility of drugs using surfactant systems (1 experiment)
13. Improved solubility of drugs using co-solvency method (1 experiment)
14. Determination of Pka and Log p of drugs.