



Gyanmanjari
Innovative University

Course Syllabus
Gyanmanjari Pharmacy College
Semester-1(M. Pharm.)

Subject: Pharmaceutical Quality Assurance Practical-I (MPHQA11505)

Type of course: Major

Prerequisite: B.Pharmacy

Rationale: Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

Teaching and Examination Scheme:

Teaching Scheme			Credits C	Examination Marks					Total Marks
CI	T	P		Theory Marks		Practical Marks		CA	
			ESE	MSE	V	P	ALA		
-	-	12	-	75	25	15	35	-	150

Legends: CI-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

List of Practicals:

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug 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 or AAS
7. Case studies on
 - Total Quality Management
 - Six Sigma
 - Change Management/ Change control & Deviations
 - Out of Specifications (OOS)
 - Out of Trend (OOT)
 - Corrective and Preventive Actions (CAPA)
 - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

