M. Pharm (Quality Assurance Techniques) 2013 Pattern (Sem I)

Advanced Analytical Techniques

Student should be able to

No.	Course Outcomes
1.	Understand Meaning and objective of research, types of research and to study preparation of research proposals and different methods of Literature survey.
2.	Study Technical writing like Research report, Research papers, Review papers, thesis writing and to acquire Presentation skills.
3.	Learn Cost analysis of the project, research organizations and procurement of research grants.
4.	Understand basic definitions/concepts of statistics like Variables and variation, sample and population, precision, accuracy and bias along with concept of Experimental design and types.
5.	Understand various parameters of Descriptive Data Analysis like and Inferential data analysis statistical measures, normal distribution, measures of relative position, measures of relationship.
6.	Learn inferential data analysis with reference to Statistical inference, the central limit theorem, parametric tests, testing statistical significance, decision making sample Z test, student's distribution (t), crossover design, variance (ANOVA), multiple regression and correlation and nonparametric tests.

Dr. S. S. Sonawane
(Subject I/c)

Research Methodology

Student should be able to

No	Course Outcome
1	Learn the principle, instrumentation and applications of various spectroscopic and chromatographic analytical techniques like UV-VIS spectroscopy, IR spectroscopy, Nuclear Magnetic Spectroscopy, Mass spectrometry, HPLC, GC, UPLC, SCFC, LC-MS and GC-MS
2	Learn the principle, instrumentation and applications of various thermal methods of analysis and electron microscopy
3	Elucidate the structure using UV, IR, NMR and MS spectral data.
4	Study and understand the effect of various solvents on absorption maxima of drugs and to learn the Beer's law limit of drugs in suitable solvent.
5	Learn and understand various multicomponent analysis technique by UV spectrophotometry for estimation of drugs in combined dosage form.
6	Perform assay of drugs official in various pharmacopoeias by UV spectrophotometry, titrimetry and HPLC. To perform validation of assay method as per USP and ICH guidelines.

(Dr. S. N. Sune)
Sub I/c

M. Pharm (Quality Assurance Techniques) 2013 Pattern (Sem I)

Advanced Quality Assurance Techniques

Student should be able to

No.	Couse Outcomes
1	Post graduate students will be able to work efficiently in Quality units of Pharmaceutical industry
2	Students will have basic understanding of total quality management and regulatory aspects fulfilling cGMP compliance.
3	Students will be more versatile candidates to work in the departments like production, research and development, quality assurance and quality control, documentation etc.
4	Student coming out of the Quality Assurance department will be self sustained making them stand differently in any associated field as entrepreneurs.

Yes
Dr Dhotas Cs
Subject I/c.

Sterile Products Formulation & Technology

Student should be able to

No.	Course Outcomes
1.	Learn preformulation, general requirements, formulation principles, packaging materials used, types, choice of containers, official quality control tests and methods of evaluation for sterile products such as SVPs, LVPs.
2.	Describe classification, general requirements, formulation, and evaluation of ophthalmic product along with ocular inserts, particulate and liposome drug delivery, protein and peptide delivery
3.	Explain merits, demerits, and application of fundamental concept of Sustained Release Parenterals
4.	Acquire the knowledge and understand the layouts of parenteral and BFS /FFS is an advanced aseptic processing technology
5.	Know the different Parenteral devices with its applications and understand the number of Hazards associated with Parental Therapy
6.	Adapt the knowledge of Good manufacturing Practices and regulatory guidelines and different process involved in Large-scale sterilization, development and validation

(Dr Thombre NA)
Subject I/C

M. Pharm (Quality Assurance Techniques) 2013 Pattern (Sem II)

Drug Regulatory Affaires

Student should be able to

No.	Couse Outcomes
1	Be familiar with Indian regulatory agencies and their modus operandi for the benefit of the society.
2	Provide knowledge of regulations governing the pharmacy profession, activities under the profession and working of different statutory bodies under the regulations.
3	Understand various certification system with special emphasis on quality, safety and efficacy.
4	Know the dug regulatory aspects for drug registration in National and International market
5	Study the different types of intellectual property rights and their benefits for the welfare of individual as well as society at large.
6	Learn American and European patent systems and treaties for intellectual property rights.

Dr. M. P. Patil

Pharmaceutical validation

Student should be able to

No.	Course Outcomes
1.	Work efficiently in Quality units of Pharmaceutical industry
2.	Understanding of concepts like prospective process validation, concurrent validation, and retrospective validation and revalidation aspects
3.	Become more compatible to work in analytical development laboratories, process development and validation departments etc.
4.	Work in the departments like production, research and development, validation, regulatory, quality assurance and quality control etc.

Dr. Deotare. A.
Subject I/c.

Bhujbal Knowledge City, MET's Institute of Pharmacy, Adgaon, Nashik

M. Pharm (Quality Assurance Techniques) 2013 Pattern (Sem II)

Quality Planning and Analysis:

Student should be able to

Course	Course Outcomes
1.	Learn basic concepts and perspective on quality, quality problems and need for quality improvement, causes of poor quality and high cost with remedy for improving quality
2.	Describe continuous process regulation for the quality control including goal, sensor, measurement of actual performance, interpretation difference between actual performance and the goal, action taken
3.	Understand culture required for the development of healthy qualitative technology with motivation, awareness, management
4.	Explain manufacturing planning for quality, responsibilities with self control- self inspection, process quality audits, statistical process control
5.	Be aware of the basics of Inspection including planning, importance of inspection, errors of measurement; testing sampling plans with sampling risks, evaluation parameters, characteristics of a good acceptance plan
6.	Know quality assurance concept; importance, planning, factors affecting, errors, reporting of quality audit and reporting results of product audit.

Dr. N. A. Thombre
(Subject I/c)

Pharmaceutical Plant Design and Operations

Student should be able to

No.	Course Outcomes
1.	Study design, layout and operational facilities considered in the manufacturing of Pharmaceutical dosage forms like Tablets, Capsules, Liquid orals, Ointments and Dry syrups.
2.	Understand cGMP Regulatory requirements of Pharma facilities, basic requirements of Factory Act and Rules and also regulations included in revised schedule M.
3.	Know the importance of different utility services required in pharmaceutical unit operations like different types of Water, steam, Compressed air and other inert gases and also various support services required in Pharmaceutical Industries.
4.	Learn the designing and operation of Quality Control lab and related parameters like effective QMS (Quality Management System), validation protocol etc.
5.	Study the basic design of effluent treatment plant (ETP) and various treatment methods required for recycling/recovery of industrial effluent/ waste products.

Dr. Ahmad S.P.

(Subject I/c)