Subject code: 13PH0705
Subject name: Quality Assurance

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objective: Upon completion of the course the student shall be able to
1. Understand the cGMP aspects in the pharmaceutical industry.
2. Appreciate the importance of documentation.
3. Understand the scope of quality certifications applicable to pharmaceutical industries.
4. Understand the responsibilities of QA & QC departments.

Teaching and assessment scheme:

<table>
<thead>
<tr>
<th>Teaching Scheme (Hours)</th>
<th>Credits</th>
<th>Theory/ Tutorial Marks</th>
<th>Practical Marks</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theory Tutorial Practical</td>
<td>3 1 0</td>
<td>4</td>
<td>10 15 75</td>
<td>0 0</td>
</tr>
</tbody>
</table>

Theory syllabus:

Unit-1

Teaching hours: 45 Hours


Unit-2


Unit-3


Unit-4

Complaints: Complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal. Document maintenance in the pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.
Unit-5 7 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management

Tutorials will be based on the above syllabus. Teaching hours: 15 Hours

Recommended References (Latest edition):
5. How to Practice GMP’s – P P Sharma.
9. ICH guidelines, ISO 9000 and 14000 guidelines.