

## BP606T- QUALITY ASSURANCE

### Detail answers (10m)

1. How complaints should be handled according to the GMP provisions? Elaborate recalling and handling of return goods.
2. What is Quality Audit? What is the scope of Quality Audit?
3. Explain the master formula record and batch formula record.

### Write notes (5m)

1. Quality review and quality documentation.
2. Batch formula records.
3. Complaints and evaluation of complaints.
4. Master formula record.
5. Explain quality Audit.
6. Give a brief account of product recall.
7. Explain about quality documentation.
8. Explain about recalling and waste disposal.
9. What is the need of distribution records in industry?
10. Explain the importance of SOP
11. Quality Audit Plan.

### Short answers (2m)

1. Master formula records.
2. Quality audit.
3. Handling of return good.
4. Records and reports.
5. SOP.
6. Waste disposal
7. Quality review.
8. Evaluation of complaints.
9. Distribution records.
10. Reports and documents.
11. Quality documentation
12. Batch manufacturing record
13. Product recall
14. Complaints
15. Types of quality audit