

BP606T- QUALITY ASSURANCE

Detail answers (10m)

1. Describe the design, construction and plant layout of Pharmaceutical Industry.
2. Discuss the responsibilities, training and hygiene of personnel.
3. Explain the design, construction, plant layout and sanitation of premises.
4. How are sanitation and sterile area are maintained in pharmaceuticals premises?

Write notes (5m)

1. Purchase specifications and maintenance of stores for raw materials.
2. Discuss the maintenance of stores for raw materials.
3. Plant layout of pharmaceutical industry.
4. Discuss about equipment selection and purchase specifications.
5. Give a brief account on the maintenance of sterile areas.
6. Write a note on personnel responsibilities.
7. What criterions are applied for the selection, purchase and maintenance of equipment?

Short answers (2m)

1. Purchase specifications.
2. Personal records.
3. Control of contamination.
4. Roles of head of production department
5. Raw materials
6. Training
7. Personnel hygiene
8. Sanitation
9. Environmental control
10. Maintenance of sterile area
11. Mix-up
12. Cross contamination