

## BP606T- QUALITY ASSURANCE

### Detail answers (10m)

1. Discuss the concept, general provisions and protocols of GLP with reference to a nonclinical laboratory study.
2. Explain the quality control tests for containers, rubber closures and secondary packing materials.
3. Explain about good laboratory practices.

### Write notes (5m)

1. Quality control test for rubber closures.
2. GLP for test and control articles.
3. Disqualification of testing facilities.
4. Testing facilities operation and disqualifying of testing facilities.
5. What are the general provisions of good laboratory practices?
6. How do you conduct a nonclinical laboratory study?
7. Quality control test for secondary packing materials.
8. Discuss the protocol for conduct of a nonclinical laboratory study.
9. Discuss the quality control tests for glass container
10. Write the quality control tests for plastic containers.
11. Write notes on types of glasses used for manufacturing pharmaceutical containers.
12. Types of rubber closures used for pharmaceutical containers.
13. Controls on animal house.

### Short notes (2m)

1. Non clinical laboratory
2. General provision of GLP.
3. Secondary packing materials
4. Test and Control articles
5. Hydrolytic resistance test for glass containers.
6. Test system
7. GLP
8. CPCSEA guidelines.
9. Restrictions on animal house.