Roll No. | | | | | | | | | | | | |

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmaceutical Quality Assurance) (2017 & Onwards)
(Sem.–1)

QUALITY CONTROL & QUALITY ASSURANCE

Subject Code : MQA-103T

Paper ID : [74701]

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

1. a) What is GLP? Discuss the essential components of GLP. Also mention the documentation and record keeping to practice GLP.

   b) Write a note on animal house set up and its documentation.

2. a) Why is proper warehousing important in pharmaceutical plants? Discuss the key features of good warehousing practice.

   b) Comment on hygiene and personal records of personnel working in pharmaceutical plants.

3. a) What is meant by in process quality control? Explain the process for IPQC of tablets.

   b) How is raw material stock documented and stored?

4. a) Mention the advantages of maintaining distribution records. Give an account of methods used for maintaining drug distribution records.

   b) What are non regulated markets? Mention the advantages of marketing drug products to such countries.

5. a) What is SOP? Mention the essential components of SOP and the advantages of writing SOP.

   b) What is quality auditing? Explain the need and methods adopted for quality auditing.

6. a) Write a note on maintenance of sanitation in pharmaceutical manufacturing premises.

   b) What is the need for drug product inspection after it has passed all quality control tests? Highlight the attributes to be evaluated for drug product inspection.