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

M.Code : 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.**

Q1. Discuss briefly.

a) Test procedures followed in a quality control laboratory (3)

b) Significance of TQM (3)

c) Electronic data handling (3)

d) Drug product inspection (3)

e) Regulated market (3)

Q2. a) Write a note on report preparation and documentation as per GLP. (7.5)

b) Discuss in details the principle of GMPs for maintenance of sterile area. (7.5)

Q3. a) Discuss the various in process quality control parameters in detail. (7.5)

b) What do you understand by Master Batch Record (MBR)? Draft a blank format from MBR. (7.5)

Q4. What is the full form of CTD? Explain in detail the various modules of CTD triangle. (15)

Q5. Discuss the following with respect to manufacturing operation and control.

a) Release of finished product (5)

b) Process deviation (5)

c) How to refer pharmacopoeias for ophthalmic, suppositories and tablets. (5)

Q6. Write note on **Any Three :**

a) QSEM (5)

b) ICH Q6 (5)

c) Good warehousing practice (5)

d) IPR (5)

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.