

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.

1. Give detailed account on the following with suitable examples.
 - a. GLP 5
 - b. State of art animal house 5
 - c. Q series guidelines 5
2. Write short notes on :
 - a. IPQC 5
 - b. QC of tablets as per US Pharmacopeia 5
 - c. ICH Q 6 guidelines 5
3. Discuss the process and preparation for inspection of pharmaceutical industry as per USFDA in detail. 15
4. Briefly discuss the following :
 - a. CTD & eCTD format 7
 - b. Three tier documentation 8
5. Write short notes on :
 - a. Cross contamination 5
 - b. CDER & CBER 5
 - c. Schedule M 5
6.
 - a. Write note on importance of IPR. 9
 - b. Elaborate on impact of time limitation on production of drugs. 6

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.