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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.**

