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

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy(Pharmaceutical Analysis) (2017 Batch) (Sem.–2)

QUALITY CONTROL & QUALITY ASSURANCE

Subject Code : MPA-203T

M.Code : 74927

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) Define the term "*Quality*"? Comment on "*Quality should be built into the product, and testing alone cannot be relied onto ensure product quality*" 2, 4

   b) Explain the role of GMP and GLP in maintaining the quality into the product. 9

2. a) What is the principal difference among the Master Formula Record, Master Production and Control Record, Manufacturing Formulae and Processing instructions and Master Manufacturing Instructions and Packaging Instructions? 8

   b) Describe the structure/contents of MFR and MPCR. 7

3. a) Define Pharmaceutical Manufacturing Documents (PMD). Explain different steps in total PMD. 2, 5

   b) Explain the guidelines for designing and implementing PMD programme 8

4. What is the legal Status of cGMP ? Explain cGMP guideline as per USFDA. 3, 12

5. a) What is the role/importance of IPQC tests in quality in any finished pharmaceutical products? Explain various IPQC test for solid and parenteral products. 2, 6

   b) Comment on the "*Sanitation of manufacturing premises" and Prevention of Mix-Ups and cross contamination*" in pharmaceutical manufacturing operations and controls in view of cGMP. 7

6. Discuss **any three** of the following :

   a) How to write of Standard Operating Procedure 3×5

   b) ICH Q6A guidelines

   c) Goods ware housing Practice

   d) CPCSEA

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.