



**MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES**
MANIPAL
(A constituent unit of MAHE, Manipal)

M. Pharm - Pharmaceutical Quality Assurance

M. Pharm Semester 1 - End-Semester Make Up Examination January 2023

PQA-MQA-102 T: Quality Management Systems

Date: 18.01.2023

Duration: - 3 Hours

Max. Marks: 75

Instructions: Answer ALL questions.

Answer the following (10 marks X 5 = 50 marks)

1. Discuss in detail about dimensions of quality 10
2. Explain the six principles of Total Quality Management in detail. 10
3. Write a note on drug returns and recalls. 10
4. Explain in detail about ICH guidelines on stability studies 10
5. Explain the importance of Statistical Process Control in pharmaceutical industries 10

Answer the following with specific answers (5 marks X 5 = 25 marks)

6. Explain the premises requirements as per WHO – GMP. 5
7. What is self-inspection? How is it helpful in assuring the quality of products? 5
8. Explain six system inspection model in detail. 5
9. Explain the importance of risk assessment 5
10. Explain the importance of benchmarking studies 5

*****End of Question Paper*****