

M. PHARM. (PHARMACEUTICAL QUALITY ASSURANCE) SEM-I (CBCS-2019  
COURSE): WINTER - 2021

SUBJECT: QUALITY MANAGEMENT SYSTEMS

Day : Tuesday  
Date : 16-11-2021

Time: 10:00AM TO 1:00  
Max. Marks: 75 P.M.

W-2021-20721

N.B.:

- 1) Attempt any FIVE questions from the following.
- 2) Figure to the right indicate FULL marks.

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- Q.1 a) Explain customer focus with reference to customer satisfaction and delight. (08)  
b) Discuss McKinsey 7s model in quality management. (07)
- Q.2 a) Explain laboratory control and material system. (08)  
b) Explain in brief IPQC and OOS. (07)
- Q.3 a) Discuss the basics of TQM. (08)  
b) Explain returns and recall procedure of pharmaceutical products. (07)
- Q.4 a) Discuss risk assessment, risk control and risk review. (08)  
b) Explain in brief Quality by Design. (07)
- Q.5 a) Discuss the statistical control charts. Write the advantages of statistical control. (08)  
b) Define benchmarking. Explain reasons and types of benchmarking. (07)
- Q.6 Write short notes on (15)  
a) CAPA  
b) ICH Q 10  
c) CFR-21 part-11

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