

MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-I Pharmaceutical Quality Assurance Regulatory Affairs : MARCH : 2022
SUBJECT: QUALITY MANAGEMENT SYSTEMS

Day : Wednesday
Date 23-03-2022

M-20721-2022

Time : 10:00 AM-01:00 PM
Max. Marks: 75

N. B.:

- 1) **Q. No. 1 and Q. No. 5 are COMPULSORY.** Out of remaining answer **ANY TWO** from each section.
 - 2) Figures to the right indicate **FULL** marks.
 - 3) Answers to both sections should be written in **SEPARATE** answer books.
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SECTION – I

- Q. 1** Discuss on Customer needs and Expectation with respect to Quality.. **(08)**
- Q. 2** Elaborate on meaning of Customer's Perception and McKansey's 7s Model. **(15)**
- Q. 3** Elaborate on ICH Q10 along with Operational Excellence. **(15)**
- Q. 4** Write short notes on **ANY TWO** of the following: **(15)**
- a) OSHAS Guidelines
 - b) Returns and Recall
 - c) Batch Review and Release

SECTION – II

- Q. 5** Discuss on ICH Q8. **(07)**
- Q. 6** Discuss on Quality Risk Assessment. **(15)**
- Q. 7** Elaborate on importance of Statistical tools in Quality management. **(15)**
- Q. 8** Write short notes on **ANY TWO** of the following: **(15)**
- a) CAPA
 - b) OOS and OOT
 - c) Principles of Six Sigma

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