

**MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)**  
**M.Pharm. Sem-I : PHARMACEUTICAL QUALITY ASSURANCE : MARCH : 2022**  
**SUBJECT: QUALITY CONTROL & QUALITY ASSURANCE**

**Day : Friday**  
**Date 25-Mar-2022**

**M-20732-2022**

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

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**N.B.**

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

- Q.1** Discuss ICH-QSEM guidelines. **(08)**
- Q.2** Discuss Personnel, Training and equipment related requirements for cGMP. **(15)**
- Q.3** Discuss important provisions of ICH Q3 & Q6 guidelines in setting up product specification. **(15)**
- Q.4** Write notes on **ANY TWO** of the following : **(15)**
- a) CPCSEA guidelines
  - b) Release of Finished Goods
  - c) IPQC of Injectable products

**SECTION – II**

- Q.5** Discuss 3 tier documentation in detail. **(07)**
- Q.6** Discuss all aspects of a CTD dossier in detail. Add a note on eCTD dossier. **(15)**
- Q.7** What are patents? Discuss important parts of a patent document. **(15)**
- Q.8** Write notes on **ANY TWO** of the following : **(15)**
- a) Quality Audit Plan
  - b) Copyrights and Trademarks
  - c) Environmental Control in Sterile area

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