**M.PHARM. (PHARMACEUTICAL QUALITY ASSURANCE)**
**SEM. – II (CBCS–2019 COURSE): Winter- 2021**
**SUBJECT : PHARMACEUTICAL MANUFACTURING TECHNOLOGY**

Day : Thursday
Date : 02-12-2021

Time : 02:00 PM-05:00 PM
Max. Marks: 75

**W-20800-2021**

**N.B.**

1) Q.1 and Q.5 are **COMPULSORY.** Out of remaining questions answer any **TWO** from each section.
2) Answer to both sections should be written in **SEPARATE** answer book.
3) Figures to the right indicate **FULL** marks.

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## SECTION – I

**Q.1** Draw and explain the layout of parenteral facility. **(08)**

**Q.2** Explain in detail features of good plant layout. **(15)**

**Q.3** Answer the following: (**5 marks each**) **(15)**

**a)** Write down legal requirements and licenses for API and formulation industry.
**b)** Describe IPQC tests for tablets and capsules.
**c)** Explain tablet coating process.

**Q.4** Write notes on the following: (**5 marks each**) **(15)**

**a)** Needle free injection and FFS technology
**b)** Lyophilization technology: Principle, process, and equipment
**c)** Factors influencing storage of raw materials and finished products in a pharmaceutical plant.

## SECTION – II

**Q.5** Explain mechanisms and biological consequences of drug-plastic interaction. **(07)**

**Q.6** Answer the following: (**5 marks each**) **(15)**

**a)** Describe quality control tests for glasses.
**b)** Explain different types of closures.
**c)** Explain CIP and SIP.

**Q.7** Answer the following: (**5 marks each**) **(15)**

**a)** Why QbD is required? Give advantages, elements and limitations of QbD.
**b)** Explain the role of design of experiments.
**c)** Discuss PAT as a driver for improving quality and reducing cost in pharmaceutical manufacturing.

**Q.8** Write notes on the following: (**5 marks each**) **(15)**

**a)** Fluidized bed coating
**b)** Explain the terms : **i)** Blister packs **ii)** Film wrapper
**c)** Factors responsible for the plant location choice

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