MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-I Pharmaceutical Quality Assurance Regulatory Affair : MARCH : 2022
SUBJECT: PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

Day : Monday
Date 28-03-2022

M-20743-2022

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 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.

SECTION – I

Q.1 Explain the techniques used to improve solubility of BCS class II drugs. **(08)**

Q.2 Define the terms purity, impurity profiles, particle size, shape and surface area. Explain in detail Pre-formulation studies. **(15)**

Q.3 Explain types of changes in bulk active chemical post approval changes (BACPAC) as part of development of pharmaceutical product. **(15)**

Q.4 Write notes on **ANY TWO** of the following : **(15)**

a) Product registration guidelines – USFDA
b) Investigational New Drugs Application
c) Stability testing during product development

SECTION – II

Q.5 Describe briefly types of packaging. Discuss the issues faced during modern drug packaging. **(07)**

Q.6 Describe large scale manufacturing techniques including formula, equipment, process, stability and quality control for semi solid dosage forms in detail. **(15)**

Q.7 What is technology transfer? Give the importance of technology transfer. Discuss various documentation involved in technology transfer. **(15)**

Q.8 Write notes on **ANY TWO** of the following : **(15)**

a) Qualitative technology models for technology transfer
b) Quality control tests for plastic and rubber container-closure systems
c) Aseptic packaging systems

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