SUPPLEMENTARY
MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-II PHARMACEUTICAL QUALITY ASSURANCE :SUMMER- 2022
SUBJECT : AUDITS & REGULATORY COMPLIANCE

Day : Monday | Time : 10:00 AM-01:00 PM

Date : 19-09-2022 | **S-20789-2022** | 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 book.
3) Figures to the right indicate **FULL** marks.

SECTION-I

Q.1 Discuss On Objectives and Management Responsibility in QMS. **(08)**

Q.2 Elaborate on role of Quality Systems in Audits. **(15)**

Q.3 Why Vendor Audits are important in Pharmaceutical Industry? **(15)**

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

a) API Vendor Audit

b) Auditing of Tablet Department

c) Auditing of Sterile Production Area

SECTION-II

Q.5 Discuss on Microbiology Lab audit check list. **(07)**

Q.6 Microbiology Audits WRT Water Systems and Packaging Components **(15)**

Q.7 Elaborate on Role Quality in Engineering Department. **(15)**

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

a) Audit of Granulation Area

b) Audit of Warehouse

c) Classifications of deficiencies

* * *