M. PHARM. (PHARMACEUTICAL QUALITY ASSURANCE) SEM-II
(CBCS-2019 COURSE): Winter - 2021
SUBJECT: AUDITS AND REGULATORY COMPLIANCE

Day: Wednesday
Date: 01-12-2021

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

W-20789-2021

N.B.:

1) **Q. No.1** and **Q. No.5** are **COMPULSORY.** Out of remaining questions answer **ANY TWO** from each section.
2) Answer to both section should be written in **SEPARATE** answer books.
3) Figure to the right indicate **FULL** marks.

SECTION-I

Q.1 Elaborate on importance of Audit Process. **(08)**

Q.2 Elaborate on classification of Audit deficiencies with examples. **(15)**

Q.3 Discuss on Role of cGMP regulation in auditing. **(15)**

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

a) Vendor Auditing
b) API manufacturing Audit
c) Audit Checklist for Granulations

SECTION-II

Q.5 Audit of Sterile Products. **(07)**

Q.6 Discuss the Audit aspects for Tablet Manufacturing. **(15)**

Q.7 Discuss the Audit process for Warehousing and Engineering stores. **(15)**

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

a) Audit Checklist for Purified Water
b) Audit Checklist for ETP
c) Audit Checklist for HVAC

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