M. PHARM (PHARMACEUTICAL QUALITY ASSURANCE)
SEM – I (CBCS – 2019 COURSE): MARCH - 2022
SUBJECT: GOOD REGULATORY PRACTICES

Day : Monday M-20711-2022 Time: 10:00 AM TO 1:00 P.M.
Date : 21-03-2022 Max. Marks: 75

N. B.:

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

SECTION – I

Q. 1 Discuss on introduction to US cGMP. **(08)**

Q. 2 Elaborate on 21 CFR part 210 and 211. **(15)**

Q. 3 Elaborate GLP regulation with respect to US FDA. **(15)**

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

a) GALP
b) Software evaluation check list
c) Global Harmonisation Task Force

SECTION – II

Q. 5 Discuss on GDP. **(07)**

Q. 6 Discuss on QMS with respect to Six Sigma Concept. **(15)**

Q. 7 Elaborate on importance of OOS and OOT with specific examples. **(15)**

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

a) Types of Validation
b) Customers Returns and Product Recall
c) VMP

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