MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-I : SUMMER : 2022
SUBJECT: DOCUMENTATION & REGULATORY WRITING

Day : Friday
Date 06-May-2022 **S-20722-2022**

Time : 10:00 AM-01:00 PM
Max. Marks: 75

N.B.:

1) Attempt any **FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.
3) Answers to both section should be written in separate Answer book.

Section I

Q.1 **a)** Discuss SUPAC documentation for manufacturing changes related to IR oral solid dosage forms. **(10)**

b) Add a note on SUPAC documentation required for site related changes for IR oral solids dosage forms. **(05)**

Q.2 **a)** Discuss the process of audit planning in pharma industry. **(10)**

b) Add a note on contents of audit report. **(05)**

Q.3 **a)** Discuss Drug Master File contents. **(07)**

b) Discuss Product Development Report in detail. **(08)**

Q.4 **a)** Write a note on Product Life Cycle Management. **(07)**

b) Discuss various modules of CTD in brief. **(08)**

Section - II

Q.5 **a)** Writ about SUPAC documentation required for composition changes to MR solid oral dosage form manufacture. **(07)**

b) Discuss Pre Approval Supplement. **(08)**

OR.

Q.6 Write short notes on the following: **(15)**

a) Advantages of eCTD

b) CAPA

c) Internal Audits

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