MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-I Regulatory Affairs : MARCH : 2022

SUBJECT: DOCUMENTATION & REGULATORY WRITING

Day : Wednesday | Time : 10:00 AM-01:00 PM
Date 23-03-2022 | **M-20722-2022** | 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) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer books.

SECTION – I

Q. 1 Discuss all components of a typical Master Formula Record. **(08)**

Q. 2 Explain 3 tier documentation in detail. **(15)**

Q. 3 Discuss content and organization of a CTD dossier. **(15)**

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

a) Product development Brief

b) Print pack specification

c) eCTD dossier

SECTION – II

Q. 5 Discuss SUPAC provisions for immediate release solid oral dosage forms. **(07)**

Q. 6 Discuss 5 phases of Audit planning in detail. **(15)**

Q. 7 Discuss USFDAs pre approval inspection program. **(15)**

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

a) CAPA

b) Audit types

c) Product Life Cycle Management

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