MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-I Pharmaceutics : MARCH : 2022
SUBJECT: REGULATORY AFFAIRS

Day : Monday
Date 28-03-2022 **M-20739-2022**

Time : 10:00 AM-01:00 PM
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 books.
3) Figures to the right indicate **FULL** marks.

SECTION-I

Q.1 Discuss principles of clinical trial research as described in ICH GCP guideline. **(08)**

Q.2 Write about medical device classification in USA. Add a note on various pathways for approval of medical devices in USA. **(15)**

Q.3 Discuss the contents of Master Formula Record, Batch Manufacturing Record and Batch Packaging Record. **(15)**

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

a) eCTD

b) Investigator's brochure

c) USFDA regulatory structure

SECTION-II

Q.5 Discuss briefly about PLM. **(07)**

Q.6 Write in detail about NDA and ANDA approval processes in USA. **(15)**

Q.7 What is SUPAC? Elaborate on the various levels of change and SUPAC documentation required for change made to composition of modified release solid oral dosage forms. **(15)**

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

a) Hatch Waxman Act

b) TGA

c) ASEAN and GCC

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