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

Day : Saturday
Date : 17-09-2022

Time : 10:00 AM-01:00 PM

S-20739-2022

Max. Marks : 75

N.B.:

1) Question **1** and **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 the advantages and importance of eCTD. **(08)**

Q.2 Discuss Hatch Waxman Act, its provisions and amendments. **(15)**

Q.3 Describe the pathway of NDA and ANDA approval in USA. **(15)**

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

a) Industry FDA Liaison
b) ICH QSEM guidelines
c) Overview of Australia TGA

SECTION-II

Q.5 Describe the process of Informed Consent in clinical trials. **(07)**

Q.6 Discuss the principles of ICH GCP. Add a note on contents of a clinical trial protocol. **(15)**

Q.7 Discuss the levels of change, test documentation and filing documentation required for SUPAC of Components and Composition of non- sterile semi solid dosage forms. **(15)**

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

a) Batch Manufacturing Records
b) HIPAA regulations
c) Institutional Review Board

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