SUPPLEMENTARY
MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-II REGULATORY AFFAIRS :SUMMER- 2022
SUBJECT : REGULATORY ASPECTS OF HERBAL & BIOLOGICALS

Day : Friday | Time : 10:00 AM-01:00 PM

Date : 16-09-2022 | **S-20779-2022** | 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 Elaborate On Plasma Master File requirements in EU **(08)**

Q.2 Explain USFDA's approach suggested for development of biosimilars. Add an elaborate note on analytical similarity demonstration for biosimilars in USFDA. **(15)**

Q.3 Discuss preclinical and clinical data requirements for registration of a biosimilar product in India. **(15)**

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

a) Biosimilar product labelling requirements in EU
b) TSE/BSE regulations in EU
c) Differentiate between generics and biosimilars

SECTION-II

Q.5 Discuss USFDA's principles for vaccine development. **(07)**

Q.6 Elaborate on Dietary Supplements regulations in USA. **(15)**

Q.7 Write about EU CTD format for herbal drug preparations. **(15)**

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

a) INH and ISBT
b) Blood bank requirements in India
c) ASU drug regulations in India

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