M. PHARM. (REGULATORY AFFAIRS)
SEM-II (CBCS-2019 COURSE): Winter- 2021
SUBJECT: REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Day: Tuesday
Time: 30-11-2021

Date: 02:00 PM-05:00 PM
Max. Marks: 75

W-20779-2021

N.B.:

1) **Q. No.1** and **Q. No.5** are **COMPULSORY.** Out of remaining attempt **ANY TWO** from each section.
2) Answer to both section should be written in **SEPARATE** answer books.
3) Figures to the right indicate **FULL** marks.

SECTION-I

Q.1 Write about Plasma Master File. **(08)**

Q.2 Discuss USA FDA Recommended Approaches to demonstrate Biosimilarity. **(15)**

Q.3 As per EU guidelines discuss various factors to be considered for comparability with Reference product while development of biosimilars. **(15)**

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

a) Post-Market Data for Similar Biologics per Indian regulation
b) Bovine Spongiform Encephalopathy (BSE) regulations for Biosimilars in USA
c) Principles for Development of Similar Biologics as per Indian guidelines

SECTION-II

Q.5 Comment on General Principles for vaccine development as per USFDA. **(07)**

Q.6 Explain the WHO guidelines on GMP for Herbal medicines (w.r.t. Personnel and Infrastructure) **(15)**

Q.7 Explain the standards recommended for Storage, transportation and expiration of blood and its components. **(15)**

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

a) International Haemovigilence Network
b) With respect to ASU drug regulations in India, what are Misbranded drugs, Adulterated Drugs and Spurious Drugs?
c) Factory Set up Manufacturing requirements for ASU Drugs as per D and C Act

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