DBX-014-1102002 Seat No. _____

M. Pharm. (Regulatory Affairs) (Sem. II)

(W.E.F. 2017) Examination

July - 2022

Regulatory Aspects of Herbals & Biologicals : MRA-202T

Faculty Code : 014

Subject Code : 1102002

Time : **3** Hours] [Total Marks : **75**

Instructions : (1) Figures to the right indicates full marks.
(2) Draw neat and clean diagram wherever required.

1 Answer the following questions: **10×2=20**

(1) What are similar biologics?

(2) What are biological products? Give any four examples of biological products.

(3) Enlist any four guidelines given by European regulatory authorities for biological products.

(4) Classify herbal medicines.

(5) Write down the importance of safety of vaccines.

(6) Which guideline is followed by European regulatory for stability testing of biologics? At which year this guideline was enacted?

(7) What is 510(k)?

(8) Enumerate the data required for preclinical studies of biologics in India.

(9) Differentiate generic products and biosimilars.

(10) What is comparability?

2 Answer any two out of the following questions: **2×10=20**

(1) What are the quality legislations for herbal products in India and US? Explain the same with similarities and differences.

(2) Write a note on Blood and Blood products regulatory requirements in India.

(3) Describe the details of ISBT and IHN.

3 Answer any seven out of the following questions: **7×5=35**

(1) Explain in detail about TSE-BSE evaluation of the product.

(2) Describe in-depth regarding plasma master file.

(3) Discuss marketing authorization requirements for vaccines in USA.

(4) Write a short note on BLA.

(5) Describe comparative measures for biological regulations in US, Europe and India.

(6) Write a brief note on Clinical Trial Application for biologics.

(7) Explain post market data for similar biologics and pharmacovigilance in India.

(8) Explain in detail about the labelling and packaging requirements of biologics.

(9) Write a brief note on different types of Marketing Authorization Procedure in EU.