

**SUPPLEMENTARY**  
**MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)**  
**M.Pharm. Sem-II PHARMACEUTICAL BIOTECHNOLOGY :SUMMER- 2022**  
**SUBJECT : BIOLOGICAL EVALUATION OF DRUG THERAPY**

Day : Wednesday

Time : 10:00 AM-01:00 PM

Date : 21-09-2022

**S-20794-2022**

Max. Marks : 75

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**N.B.**

- 1) Q.1 and Q.5 are **COMPULSORY**. Out of the remaining attempt any **TWO** questions from each section.
  - 2) Figures to the right indicate **FULL** marks.
  - 3) Answers to both the section should be written in **SEPARATE** answer book.
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**SECTION – I**

- Q.1** Write the difference between pre-clinical testing and clinical testing. (08)
- Q.2** What do you mean by bioassay? Describe different types of bioassays giving suitable examples. (15)
- Q.3** What are different sources of pyrogens? Describe the official tests to identify pyrogens in the parenteral formulation. (15)
- Q.4** Write note on any **TWO** of the following: (15)
- a) Recombinant Hormones
  - b) Biomedicine in infectious disease
  - c) LD 50 determination

**SECTION – II**

- Q.5** Discuss the parameters for evaluation of safety of vaccines. (07)
- Q.6** Describe in detail the cellular mechanism of RNA interference and discuss its significance. (15)
- Q.7** Write in detail applications of Pharmacokinetics in new drug development of biopharmaceuticals and designing of dosage forms. (15)
- Q.8** Write notes on any **TWO** of the following: (15)
- a) Regulatory aspects of clinical testing
  - b) Bioequivalence and its importance
  - c) Antisense therapy

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