2 ½ Hours **Total Marks: 60**

Note: 1) All questions are compulsory.
2) Draw neat, labelled diagrams wherever necessary.
3) Figures to the right indicate full marks.
4) All questions carry equal marks.

Q1 Answer the following (Any Two): **12**

a) What do you mean by Small molecules as biologics and biosimilars? Discuss any 2 distinguishing points between large molecules and small molecules.
b) What do you mean by Biogenerics? Give any 2 examples of USFDA approved biogenerics and state its use in therapeutics.
c) Discuss Enzymes as Biologics. Give 2 examples of the USFDA approved Enzymes used in therapeutics and diagnostics.
d) Elaborate on the role DCGI in the regulatory process of Biosimilars in India.

Q2 Attempt the following (Any two): **12**

a) What is cell line? Explain the stability of the cell lines.
b) What is scale up manufacturing? Explain with some tips to help scale up manufacturing.
c) Explain the steps in the production of monoclonal antibodies.
d) Explain the concept of biosimilars with examples.

Q3 Give an account of the following (Any two): **12**

a) How Mass spectra and Fluorescence spectra can be helpful in biosimilar characterisation?
b) Give details of any 3 proteolytic enzymes which are used while characterization of biosimilar products.
c) Elaborate on Isoelectric Focusing (IEF) method used for analysis of post translation modifications in biosimilar products.
d) How size and purity of biosimilar product can be analysed by PAGE?

Q4 Answer the following (Any two): **12**

a) Explain in detail – Regulation of biosimilars.
b) Discuss India-biosimilar regulatory requirements in detail.
c) Explain in detail – Biological product.
d) Elaborate on – Abbreviated licensure pathway.

Q5 Write short notes on (Any Three): **12**

a) Vaccines as Biologics.
b) Manufacturing conditions
c) Virus filtration
d) Western blotting for biosimilar analysis
e) Bioassay using BioLayer Interferometry (BLI) technology
f) Clinical trials initiation and filling of biosimilar application.

****