

**2022**

**M.Sc.**

**4th Semester Examination**

**BIOMEDICAL LABORATORY SCIENCE  
AND MANAGEMENT**

**PAPER—BML-402**

**CLINICAL RESEARCH AND BIO-INFORMATICS**

*Full Marks : 50*

*Time : 2 Hours*

*The figures in the margin indicate full marks.*

*Candidates are required to give their answers in their own words as far as practicable.*

*Illustrate the answers wherever necessary.*

**Group—A**

Answer any *four* questions.

4×2

1. What do you mean by teratogenicity?

*(Turn Over)*

2. What do you mean by 'Schedule-Y' in clinical trial ?
3. Write the full formed DCGI and IPR.
4. Write the full forms of US-FDA and HIPPA.
5. What is FASTA format ?
6. What do you mean by 'protein docking' ?

**Group—B**

Answer any *four* questions.

4×4

7. What is pre-clinical research ? Write the importances of pre-clinical research in drug development.  
2+2
8. What is Pharmacokinetics ? State the different steps of pharmacokinetics.  
1+3
9. State the importances of pharmacovigilance in clinical research.

10. Write the guide lines for patenting a product as per GOI rules.
11. Briefly discuss about the types of decision taken by 'Ethical Committee' during the screening of clinical trial.
12. Write the utility of 'BLAST' programme for analysis of nucleic acid.

**Group—C**

Answer any *two* questions.

2×8

13. Discuss in details about conduction of phase - I, II, III, IV clinical trials as per rules of GOI.
14. How will you measure LD<sub>50</sub> & ED<sub>50</sub> values of a drug? What do you mean by hyperreactive, hyporeactive and normoreactive individuals in response to a particular drug. 4+4
15. Discuss about the in silico design of PCR Primers.

16. What is PDB? How do you assess the protein structure using RCSB? 4+4

*[Internal assessment - 10]*

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