

M.Sc. 4th Semester Examination, 2024

**BIO-MEDICAL LABORATORY SCIENCE
AND MANAGEMENT**

(Clinical Research & Health Informatics)

PAPER – BML-402

Full Marks : 50

Time : 2 hours

The figures in the right hand margin indicate marks

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

GROUP – A

Answer any **four** of the following : 2×4

1. What is Pharmacodynamics ?
2. Define 'Schedule-Y'.

3. What is preclinical study ?
4. Write the full form of DCGI and IPR.
5. What is clinical research ?
6. Write the application of the NCBI BLAST.

GROUP – B

Answer any **four** of the following : 4 × 4

7. Describe the objective and conditions of Phase I clinical trial. 4
8. Describe single blind and double blind clinical study with their importances. 4
9. “Preclinical research is the foundation of clinical research” – Justify the statement critically. 4

10. Write the criteria of IPR and the steps adopted for filing in this purpose. 4
11. Write the steps of in-silico PCR primer design. 4
12. What is gene mutation? How drugs can induce gene mutation? 2 + 2

GROUP – C

Answer any two of the following : 8 × 2

13. Define Pharmacovigilance. What are the different functions of pharmacovigilance. Write the regulatory authority in India for this purpose. 2 + 4 + 2
14. Describe the process of conduction of clinical trial phase-II and phase-III for drug development. 4 + 4

15. What is drug bioavailability? Discuss the factors affecting drug bioavailability. State the nutrient-drug interaction in this context. $2 + 4 + 2$
16. Define acute, subacute and subchronic toxicity. How do you explore dose dependent response of a drug? Define TD_{50} . $3 + 3 + 2$

[Internal Assessment – 10 Marks]
