

M. Sc.

2018

4th Semester Examination

BIO-MEDICAL LABORATORY SCIENCE AND MANAGEMENT

PAPER—BLM-404

Subject Code—22

Full Marks : 40

Time : 2 Hours

The figures in the right-hand margin indicate full marks.

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

Illustrate the answers wherever necessary.

Answer Q. No. 1 and any *three* from the rest.

1. Answer any *five* questions : 5×2

(a) Write the names of any four factors those influence the drug toxicity.

(b) Why are undernourished patients more susceptible to drug toxicity ?

(Turn Over)

- (c) Write any two domains covered under pharmacovigilance.
- (d) Write the full form of DCGI and UG-FDA.
- (e) Define teratogen.
- (f) What do you mean by 'Bio Pharmaceutics'.
- (g) What is preclinical study ?
- (h) Write the full form of ADR and IPR.
2. (a) Describe in brief the design of study under Phase I, II, III and IV clinical research.
- (b) Define LD₅₀. 8+2
3. (a) What do you mean by hyporeactive, hyperreactive and normoreactive individuals.
- (b) Write the possible mode of action of metagenic agent. 6+4
4. (a) What are the guidelines to obtained patent on a research output ?
- (b) State the factors that modulate the bio-efficacy of a drug. 4+6

5. (a) "Sense of ethic is most important in *clinical research*".
Justify the statement.
- (b) "Regular monitoring and inspection of drug handling organisation are two vital process for quality outcome in that sector"—critically analyse the statement.
- 5+5
6. (a) "Pre-clinical research in the Platform of clinical research"—Establish it with example.
- (b) Write the submission process to obtain IPR on research output.
- 5+5
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