

**M. Sc.**

**2017**

**4th Semester Examination**

**BIO-MEDICAL LABORATORY SCIENCE AND MANAGEMENT**

**PAPER—BLM-404**

*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 of the following : 5×2

(a) What do you mean by acceptable mutation ?

(b) Write the full form of IEC and IPR.

(c) What do you mean by drug adaptation ?

(d) Define pre-clinical trial of drug.

*(Turn Over)*

- (e) Write the nature of biochemical reaction operated in liver of second phase of drug bio-transformation.
- (f) Write the full form of SAE and FDA.
- (g) What do you mean by therapeutic dose of any drug?
- (h) Define pharmacovigilance.
2. (a) Write in brief about the regulators of drug toxicity.
- (b) State the mode of action of the drug for the onset of cancer.
- (c) How does the drug can induce macro mutation ?
- 3+4+3
3. (a) Describe in brief about the factors that interfere the drug bioavailability.
- (b) "Drug absorption from intestine is also controlled by dietary components"—Justify the statement.
- (c) Why same dose of the drug is not effective for all individuals in the community suffering from same disease ?
- 3+4+3

4. (a) Write in brief the Phase-I and Phase-II clinical trials of the drug in brief.
- (b) State the major domains of investigation of pharmacovigilance department.
- (c) Define acute, sub-chronic and chronic toxicity. 5+2+3
5. (a) Define clinical research.
- (b) State the role of basic researches in the field of clinical research.
- (c) What do you mean by post-drug approval?
- (d) Describe bio-pharmaceutics in brief. 2+3+2+3
6. (a) Write the major roles delivered by the 'IEC'.
- (b) State the protocol adopted for new drug discovery process.
- (c) What are the phases of submission IPR in clinical research? 3+4+3
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