M.Sc.

2016

4th Semester Examination

BIOMEDICAL 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 LD_{50} and ED_{50} values.

(b) What do you mean by drug biotransformation ?

(c) Write name of any two indicators of the assessment of chronic reproductive toxicity.

(d) What do you mean by Phaze-I clinical trial for a drug ?

(e) What is IPR ?

(f) Write the full form of DCGI and US-FDA.

(g) What do you mean by Pharmaco Vigilance ?

(h) Write the process of pre-drug approval.

2. (a) Write any two features of sensor for the assesment of reproductive toxicity.

(b) Why drug toxicity is noted after the application of normal dose of drug in protein undernutrient patient ?

(c) "Sperm Count is the sensor of chronic reproductive toxicity evaluation but Sperm viability is the sensor of acute reproductive toxicity assessment". Justify the statement. 2+4+4

3. (a) Write the clearance of drug from our body

(b) State in brief about bioactivation of drug in VIVO.

(c) Write in brief about different phases of clinical trial for establishing an agent as drug. 3+3+4

4. (a) State the importance of patent of your research output.

   (b) Write the function of Ethics Committee in clinical research.

   (c) State the importance of pharmacovigilance. 3+3+4

5. (a) What do you mean by 'Biopharmaceutics'?

   (b) State the functions of 'Drug Regulatory Authorities.'

   (c) Write in brief about pre-drug approval. 3+4+3

6. (a) State about the conduction of clinical trial of a drug at phase II, III & IV in brief.

   (b) Write in short about post drug approval.

   (a) What do you mean by ADR? 6+2+2
