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NC-02010306

Seat No. _____

M. Pharm. (Sem. I) (CBCS) Examination

January – 2017

Quality Assurance : Paper - I
Biological Evaluation & Clinical Research (Theory)

(Core Subject - I)

Time : **3** Hours] [Total Marks : **80**

Instructions : (1) Answer and tie up both the sections separately.
(2) Figure to the right indicates marks.
(3) Answer the three (03) questions from each section.
(4) Question one (1) and question Five (05) are compulsory.
(5) Draw neat and clean diagrams as required.

SECTION - I

1 Write any seven out of eight : **14**

(a) Give examples of human teratogens.

(b) Explain "Pharmacokinetic study is very important.

(c) Give objectives for bio-analytical sample preparation.

(d) Comment: Animal test can replace human whole blood test.

(e) Define: Monolithic columns.

(f) What is therapeutic equivalent?

(g) Define: De-pyrogenation.

(h) What are the key points to successful use of solid-phase extraction for bio analytical sample preparation?

2 Answer the following :

(a) What do you mean by Preclinical Drug Evaluation? Explain in brief sub acute and chronic toxicity studies. **7**

(b) Explain the objective and protocol design of Clinical Research Protocols? **6**

3 Answer the following

(a) Write a Short note on "Helsinki declaration" **7**

(b) Write a Short note on Good Clinical Practices **6**

4 Answer the following :

(a) Give method development scheme for Mixed mode in SPE. **7**

(b) Give comparison of pyrogen test in between BP, IP and USP. **6**

SECTION - II

5 Write any Two out of three **14**

(a) Explain in detail about the membrane filtration.

(b) Give the General Principles, Scope & limitations of Bioassays.

(c) Describe the bioassay which requires dose response curve (DRC).

6 Answer the following :

(a) Define LD_{50}, ED_{50}, Explain method for determination of LD_{50}. **7**

(b) What is mutagenicity & carcinogenicity? Discuss their biochemical mechanism and measurement techniques in detail. **6**

7 Answer the following :

(a) Give the application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems. **7**

(b) What is Teratogenesis? Explain its mechanism and testing in detail. **6**

8 Answer the following :

(a) What is bioavailability? Explain regulatory aspect for Bioavailability and Bioequivalence. **7**

(b) Discuss principle, procedure, advantages and disadvantages of LLE. **6**