Roll No. | | | | | | | | | | | | |

Total No. of Pages : 02

Total No. of Questions : 10

M.Sc (Clinical Research) (2018 Batch) (Sem.-1)

FUNDAMENTALS OF CLINICAL RESEARCH

Subject Code : MSCR-102-18

Paper ID : [75606]

Time : 3 Hrs. Max. Marks : 70

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains FIVE questions carrying FIVE marks each and students have to attempt any FOUR questions.**
3. **SECTION-C contains FOUR questions carrying TEN marks each and students have to attempt any THREE questions.**

SECTION-A

Q1 Write briefly :

a. Name major objectives of phase 0 clinical trials.

b. Define intellectual property rights.

c. Expand the term and define TRIPS.

d. Name three major issues in conduct of clinical trials.

e. Write the basic steps of drug development process.

f. Define placebo. Write two major disadvantages of using placebo.

g. Define investigational new drug application. (INDA).

h. Define lead identification and optimization.

i. Plot a graph to depict difference between controlled release and prolonged release formulation.

j. What should be the ideal half life for making sustained release products?

SECTION-B

Q2. Briefly describe the various pharmacological approaches to drug discovery.

Q3. Stepwise describe the high throughput screening (HTS) process.

Q4. Describe the prerequisites for patents registration

Q5. Describe the methods of conducting phase-IV clinical trials.

Q6. Differentiate between quality control and quality assurance process.

SECTION-C

Q7. Describe the objectives of various phases of clinical trials.

Q8. Write short notes on the following :

a) Total quality management.

b) Properties and advantages of controlled release formulations.

c) Biopharmaceutical classification system.

Q9. Describe the various types of intellectual property.

Q10. Describe the drug development process.