



AJEENKYA

D Y PATIL UNIVERSITY

End Term Examination (December 2019)

School: SOM

Program: MSc CLINICAL RESEARCH

Course: CLINICAL EVALUATION

Course Code: MGT550

Semester: 1st

Max Marks: 50 marks

Duration (mins): 150 mins

Instructions to the students

- 1) **The Question paper consists of two sections - Section I and Section II.**
- 2) **All questions are compulsory.**
- 3) **Neat flow charts or diagrams must be drawn wherever necessary**
- 4) **Figures on the right indicate full marks**

SECTION 1

Q 1) Answer the following:

[2x5=10]

- a) Explain with example inclusive and exclusive criteria in clinical studies.
- b) Give examples for rubrics rating scale.
- c) What is blinding? Also give the need for blinding.
- d) What are the reasons for decline in participation in clinical trials?
- e) Write a note on clinical outcomes.

Q 2) Attempt any two of the following:

[5x2=10]

- a) Explain in detail the various stages of clinical evaluation.
- b) Describe the informed consent process in – children, pregnant ladies and illiterate people.
- c) Describe the various tools used for clinical evaluation.
- d) Explain in detail Specific strategies for retaining participants in a clinical study.

Q 3) Attempt any one of the following: [5x1=5]

- a) Explain diagrammatically various types of concept map configurations. Take an example and illustrate one type of concept map configuration.
- b) Elaborate in detail various types of blinding in clinical trials.

SECTION II

Q 1) Answer the following: [2x5=10]

- a) Explain in- vivo and in-silico studies.
- b) Describe clinical trial end-points.
- e) Explain with examples physical and chemical agents for teratogenesis.
- f) What is humanized mouse?
- g) Describe the terms- Insertion mutation and deletion mutation.

Q 2) Attempt any two of the following: [5x2=10]

- a) What is mutagenicity? Explain the classification criteria for mutagenic substances.
- b) Explain infectious agents as teratogenic agents.
- c) What is reproductive toxicity? Explain in detail the classification of reproductive toxicity.
- d) Explain in detail various steps in carcinogenesis with the help of a flow diagram.

Q 3) Attempt any one of the following: [5x1=5]

- a) Describe the types of base – substitution. Explain with the help of a disease how Base-substitution leads to mutation?
- b) What is teratogenesis? What are the principles that guides the study and understanding of teratogenic agents and their effects on developing organisms.

***** ALL THE BEST *****