

B.Sc. (Sem.-IV) Examination

CC 205

Health Hygiene

May-2017

Time : 3 Hours]

[Max. Marks : 70

Que-1 Answer the following (Any two) 14

- A. Discuss the phases I to IV of Clinical trials.
- B. Write a note on planning and designing of clinical study.
- C. Explain PK/PD Modeling.
- D. Describe Biomarker and its types.

Que-2 Answer the following (Any two) 14

- A. Describe structure and content of a typical clinical study report.
- B. Explain the tools and software used in conducting Clinical trials.
- C. Describe study population and sample size on data analysis in clinical report.
- D. Discuss the importance of publication bias in clinical study report.

Que-3 Answer the following (Any two) 14

- A. Discuss the role of IND in clinical research.
- B. Explain social and political issues related to clinical study.
- C. Describe the role and importance of agencies in drug approval process.
- D. Write a short note on current regulatory requirements in clinical research.

Que-4 Answer the following (Any two) 14

- A. What is Hypercholesterolemia? Discuss a case study on drug CRD5.
- B. Report model for clinical study made on treating acne using Finasteride drug.
- C. Discuss importance and finding of case study on Anti-mullerian drug on hormonal secretion.
- D. Discuss the criteria to be measured for Pre-clinical trials.

Que-5 Answer the following (All are compulsory) 14

1. Write the full form of NDA.
2. Name any two agencies for drug approval in India.
3. What is the use of SPSS in clinical analysis?
4. Define Bioequivalence.
5. Give difference between Pharmacokinetic and Pharmacodynamic.
6. What is Belmont report?
7. What are double blinding techniques?
8. Why Human clinical studies are widespread in developing countries?
9. What do you mean by Placebo?
10. Give full form of CIOMS and WMA.
11. Write the importance of Baseline in clinical report.
12. Enlist the components of clinical report.
13. What is bioavailability in clinical research?
14. Name the parties having conflicting interest in clinical studies.