0405N218

Candidate's Seat No : _____

BSc Sem.-4 Examination
CC 205
Health & Hygiene
May 2022

Time : 2-00 Hours] **[Max. Marks : 50**

1. (A) Write down on Drug development and clinical trials. 7
   (B) Explain response variables and biomarkers. 7

2. (A) Discuss planning and design of clinical study. 7
   (B) Write brief detail note on concept of Bioavailability and Bioequivalence. 7

3. (A) Explain tools and software use in clinical studies. 7
   (B) Give detail on delays and conflicts of interest. 7

4. (A) Discuss clinical data management and biostatics. 7
   (B) Discuss the guidance for reporting and publication bias in clinical report. 7

5. (A) Give details note on regulation in clinical research. 7
   (B) Discuss politics of research on women and religion. 7

6. (A) Discuss the current regulatory requirements and over view for new drug application. 7
   (B) Explain regulation of agency for drug approval in India. 7

7. (A) Explain the Belmont report. 7
   (B) Explain investigational new drugs regulation. 7

8. (A) Discuss drug accountability. 7
   (B) Write down any two-case study on clinical research. 7

9. Answer the following (Any eight) 8

1. Define: Biomarkers.
2. Function of clinical trials.
3. What is PK/PD modeling.
4. Define: Baseline issues.
5. Full form of NDA.
6. Function of FDA.
7. Define: BLAST.
8. Explain Thrombosis.
9. What is Risk identification?
10. Define suppression.
11. Planning of clinical study.
12. Two agency name of drug approval in Gujarat.