AV – 2488

Fifth Year Pharm D. Examination

CLINICAL RESEARCH

Paper - 5.1

(USC – 35133)

P. Pages : 2

Time : Three Hours] [Max. Marks : 70

Note : (1) Answer any **Five** questions from Q. No **Two** to **Nine** questions.
(2) Question No. **One** compulsory.
(3) Illustrate your **answer wherever** necessary with the help of neat sketches.
(4) Use pen of **Blue/Black ink/refill** only for writing the answer book.

1. Solve the following :—

   (a) Discuss various phases of clinical trials. 8

   (b) Explain the roles and responsibilities of principal investigator. 7

2. Define drug discovery and development. Explain in detail various stages in the drug discovery in a pharmacological perspective. 11

3. Write about CDSCO guidelines for good clinical practice. 11

4. Write note on data requirements for approval of clinical trials. Write about the regularity requirements in USA for clinical development of drug. 11

5. (a) Give note on informed conscent process.

   (b) Write about role and responsibility, composition of institutional ethics committee. 11

6. (a) How the following documents are designed for clinical study :—

   (a) Protocol

   (b) CRF. 6

(b) Write about the responsibility of the sponsorer in clinical trials. 5

7. (a) Write about the Data management and its components in clinical development.

(b) Comment on the safety monitoring in clinical trials. 11

8. Discuss various toxicological approaches to drug discovery. Explain the role of drug characterisation in drug discovery. 11

9. Write short notes on :—

(a) Abbreviated New drug application submission.

(b) Contract research coordinators. 11