Code No: PD501

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm.D V Year Supplementary Examinations, October - 2019
CLINICAL RESEARCH

Time: 3hours **Max.Marks:70**

Answer any five questions
All questions carry equal marks
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1. Describe the following approaches for the drug discovery process:
   a) Drug characterization
   b) Dosage form. [7+7]

2. Describe the importance of the following in Drug Development process:
   a) Pharmacological
   b) IND application. [7+7]

3.a) What are the different phases of clinical trials. Explain in detail.
b) Write about CDSCO guidelines. [7+7]

4. Write about the following:
   a) Methods of post marketing surveillance
   b) Challenges in the implementation of guidelines. [7+7]

5. Describe the following:
   a) Overview of regulatory environment in Europe.
   b) Composition, responsibilities and procedures of IEC [7+7]

6. Describe the responsibilities of the following personnel as per ICH GCP:
   a) Sponsor
   b) Investigators [7+7]

7.a) Describe the protocol involved in the Abbreviated NDA submission.
b) Write about designing of clinical study documents. [7+7]

8.a) Discuss the overview on Ethical guidelines in Clinical Research.
b) Write about the Safety monitoring in clinical trials. [7+7]

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