Write short notes on:

1. a) Write the in-vitro and animal toxicity tests required for new drug development.
   b) What are preclinical evaluation methods for potential antiepileptic new chemical entity?

2. a) What are the ethical and regulatory issues in use of animals in biomedical research?
   b) Composition and functions of Institutional Ethics Committee for research in human subjects.

3. a) Methods of Pharmacovigilance with their advantages and limitations
   b) Pharmacogenomics interlink with pharmacovigilance, giving examples.

4. a) What are the inclusion and exclusion criteria of papers in meta analysis. What is the advantage of meta analysis?
   b) What are the methods and implications of drug utilization studies?

5. a) Difference between partial agonist and inverse agonist giving suitable examples.
   b) Define median lethal dose and median effective dose and their importance in Therapeutics.

6. a) Define bioavailability and how it is determined. Give suitable examples.
   b) What is the difference between pharmaceutical equivalent and therapeutic equivalent? Give suitable equivalence.

7. a) Role of Placebo in clinical trials.
   b) Mention advantages and disadvantages of fixed dose combination.
8. a) Principles and steps in preparing National List of Essential Medicine (NLEM)  
   b) Potential uses of NLEM in rational therapeutics.

   b) Nanotechnology in drug delivery system.

10. a) Define drug dependence and its mechanisms.  
     b) Principles of treatment of drug dependence with suitable examples.