Time: 3 hours
Max. Marks: 100

Important instructions:
- Attempt all questions in order.
- Each question carries 10 marks.
- Read the question carefully and answer to the point neatly and legibly.
- Do not leave any blank pages between two answers.
- Indicate the question number correctly for the answer in the margin space.
- Answer all the parts of a single question together.
- Start the answer to a question on a fresh page or leave adequate space between two answers.
- Draw table/diagrams/flowcharts wherever appropriate.

Write short notes on:

1. a) Enumerate patient safety and pharmacovigilance.  
   b) Pharmacovigilance programme of India (PVPI).

2. Mention different endothelin receptors, drug acting on endothelin receptor, their therapeutic use, adverse effect and precautions.

3. Procedure for Investigational New Drug (IND) and New Drug Applications (NDA) as per Schedule Y.

4. a) Proof of concept in clinical trial.  
   b) Therapeutic misconception

5. a) Define biomarker.  
   b) Uses of biomarkers for personalized medicine.  
   c) Biomarker regulatory validation.

6. a) Therapeutic drug monitoring of immunosuppressive drug.
   b) Accreditation of the therapeutic drug monitoring laboratory.

7. a) Signal review of medicinal product  
   b) Biovigilance

8. a) Novel analgesic targets for treatment of pain.  
   b) Neuronal nicotinic receptors as targets for novel analgesics.

9. a) Compensation in clinical trial.  
   b) Role of Ethics Committee as per amendment of Schedule Y.

10. a) Enumerate various histaminic receptors.  
    b) Clinical use of anti-histaminics, adverse effects and precautions.