PHARMACOLOGY

PAPER – IV

PHARM/D/16/34/IV

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) What is a surrogate marker in a clinical trial? 5+5
   b) What are their merits and demerits?

2. a) Role and responsibilities of DSMB in clinical trials. 5+5
   b) Clinical trial registry of India – Role and functioning.

3. a) Methods for causality assessment. 5+5
   b) Timelines for reporting of serious adverse events in clinical trials.

4. a) What are protocol violations in a clinical trial? 5+5
   b) Guidelines for accredition of ethics committees in India.

5. a) Informed consent in clinical trials. 5+5
   b) Ethical issues in clinical trials in vulnerable population.

6. a) Indications, limitations and advantages of therapeutic drug monitoring. (4+2+2)+2
   b) Examples of drugs for which therapeutic drug monitoring is recommended.

7. a) What are essential medicines? 4+6
   b) National List of essential medicines.

8. a) Procedure and requirements for New Drug Application (NDA) as per schedule in India. 4+3+3
   b) Conditions where waiver of phase III clinical trial can be considered.
   c) Issues regarding compensation in clinical trial related injury.

9. a) Responsibilities of sponsor of a clinical trial as per the Indian GCP guidelines. 5+5
   b) Orphan drugs.

10. a) Biosimilars 5+5
    b) Pharmacotherapy of Alzheimer's disease.

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