

FINAL EXAM
DECEMBER 2016

NATIONAL BOARD OF EXAMINATIONS

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 accreditation 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.
