

PHARMACOLOGY

PAPER-IV

Time: 3 hours

Max. Marks:100

PHARM/D/19/34/IV

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. Give an outline about calculation of compensation if the trial participant suffers serious adverse event in a clinical trial. Add a note on the recommended time line of paying compensation by the sponsor after a trial related serious adverse event. 7+3
2. Write briefly how you would help the sponsor to establish a BA-BE study Centre for regulatory BA-BE studies following newer rules in India. 7+3
3. Describe with examples the mechanisms of action of siderophore antibiotics. How could these agents be used to overcome bacterial resistance? 7+3
4. Write in brief about recent advances in the treatment of rheumatoid arthritis. How can you prevent some of the adverse effects of biologics? 8+2
5. Discuss briefly about the newer anticoagulants. What are their advantages and disadvantages compared to conventional anticoagulants? 6+4
6. Write a brief note on ethical considerations on research involving bio banking. Give your comments on broad vis-a vis blanket consent for using human biomaterials. 6+4
7. Enumerate the principles of research among vulnerable population according to recent changes in ethical guidelines in India. What are the protective mechanisms to safeguard their interest? 6+4
8. Elaborate with examples the recent advances, future prospects and challenges of antisense oligonucleotide therapy. 6+2+2
9. Enumerate the essential and additional elements of informed consent documents according to recent Indian Guidelines. In which conditions Ethics Committee may grant waiver of consent? 7+3
10. Give an outline of expedited drug approval pathways. Make a brief note on application of artificial intelligence in pharmacovigilance. 5+5
