FINAL EXAM
DECEMBER 2019
 NATIONAL BOARD OF EXAMINATIONS

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

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