

FACULTY OF PHARMACY

**M. Pharmacy (Pharmacology) II-Semester (PCI) (Supply.) Examination,
January 2020**

Subject : Clinical Research and Pharmacovigilance

Time: 3 Hours

Max. Marks: 75

Note: Answer any Five Questions. All Questions Carry Equal Marks.

- | | |
|---|----|
| 1. a) Explain the structure and content of an informed consent process. | 8 |
| b) Describe briefly ICH-GCP guidelines. | 7 |
| 2. Explain the roles and responsibilities of | |
| a) Investigator. | 7 |
| b) Contract research organization. | |
| 3. Define ADR. Explain the detection and reporting methods of ADRs. | 15 |
| 4. a) Define pharmacovigilance. Write a note on role of pharmacovigilance in India. | 10 |
| b) Describe briefly about spontaneous reporting system. | 5 |
| 5. a) Write a note on pharmacoepidemiology. | 8 |
| b) Discuss about the different types of adverse drug reactions with examples. | 7 |
| 6. Describe the ICMR guidelines for biomedical research. | 15 |
| 7. Explain the methods of Safety monitoring in clinical trials | 15 |
| 8. a) Explain the significance of safety monitoring in clinical trials | 7 |
| b) What are the various statistical methods for evaluating medication safety data. | 8 |

Pharmacology Question Papers Pharmacy Third Year

Briony Hudson, Maureen Boylan



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2024-25 RRB Pharmacist Solved Papers and Practice Book YCT Expert Team , 2024 25 RRB Pharmacist Solved Papers and Practice Book 208 395 E This book contains 18 sets solved papers and practice book and covers paper I to paper V A *Textbook of Pharmacology - III* Dr. Gorakshnath V. Paunikar , Dr. Minal Ghule , Dr. Satnam Singh , Mr. Kirankumar H. Dhawale , Dr. V. Suresh,2025-01-07 It is with great pleasure that we introduce the book Pharmacology III This book has been meticulously designed in accordance with the syllabus prescribed by the Pharmacy Council of India for Bachelor of Pharmacy students Every effort has been made to present the subject matter in a simple easy to understand language To aid comprehension the book includes numerous diagrams and flowcharts that simplify complex concepts for students It is our sincere hope that this book will serve as a valuable resource for both students and academicians We hope this book will receive a positive response from both students and educators Constructive feedback from professionals in the field is welcome and we acknowledge that any errors or omissions are our responsibility We would be grateful if readers bring such issues to our attention

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