

[Total No. of Questions - 15] [Total No. of Printed Pages - 2]  
(2064)

14822

**M. Pharmacy 2nd Semester Examination**  
**Intellectual Property Rights & Drug Regulatory Affairs**  
**MP-021**

**Time : 3 Hours**

**Max. Marks : 90**

*The candidates shall limit their answers precisely within the answer-book (40 pages) issued to them and no supplementary/continuation sheet will be issued.*

**Note :** Attempt one question from Part A, three questions from Part B and seven questions from Part C.

**PART - A**

1. What is Indian Patent Act, 1970? Discuss various steps for filing a Patent.
2. Explain various stages of clinical trials. (1×25=25)

**PART - B**

3. What is mechanism for protection of intellectual property patents?
4. What are international patenting requirement procedures?
5. Give social and environmental benefits of modern biotechnology.
6. Discuss technology transfer commercialisation related aspects. (10×3=30)

**PART - C**

7. Give guidelines of WHO regarding drug regulatory affairs.

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8. What are the requirements of GLP?
9. Give composition of Drug Regulatory control authorities.
10. Write down regulations on manufacture of drugs in India.
11. What is meant by ISO : 9000 series?
12. State drugs and cosmetics acts and rules.
13. Give issues of confidentiality in drug regulatory affairs.
14. Write down important regulations related to export of drugs.
15. What are the steps for submission of marketing application in India. (7×5=35)