[Total No. of Questions - 15] [Total No. of Printed Pages - 2]
(2063)

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B. Pharmacy 2nd Semester Examination

Intellectual Property Rights & Drug Regulatory Affairs

MP-021

Time : 3 Hours **Max. Marks : 60**

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 all parts of question paper.

PART - A

(Attempt any one question carrying 18 marks)

1. Explain intellectual property and discuss the laws which regulate such property.
2. Explain the requirements of CGMP for production area of pharma. Industry with reference to USFDA. Also mention the documents to be maintained in pharma industry according to GMP.

PART - B

(Attempt any three questions carrying 7 marks)

3. Give essential features of clerical trails.
4. Compare the requirements of WHO guidelines and ISO 9000 series.
5. Write GLP for requirements.
6. Write social and environmental benefits of modern biotechnology.

PART - C

(Attempt any seven question carrying 3 marks)

7. Write a note on regulatory approval pathway.
8. State is vivo bio equivalence documentation.
9. How do you prepare common technical documents as per ICH guidelines?
10. Explain “trademark” and “service mark”.
11. State provisions of schedule as of drug and cosmetic act.
12. Give the components of application for marketing pharmaceuticals in CIS.
13. What is TRIPS, give its function?
14. How do you maintain Master Formula?
15. What is “Patent Pending” and “Patent Applied for”.