Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - Dec-2017

[Time: 3 Hours] [Max. Marks: 75]

Drug Regulations and Intellectual Property Rights

Q.P. CODE: 5111

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. What are stages of patenting? Describe them.
2. What is the impact of GATT on developing countries?
3. Describe the impact of trademarks on Pharmaceutical Industry.
4. Explain the role of USFDA and CDSCO in controlling drug regulations.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Write the conditions to be satisfied by an invention to be patentable.
6. Explain advantages and limitations of patents.
7. Describe the provisions accepted under TRIPS.
8. What are the features of WIPO?
9. What are intellectual property rights? Briefly explain each property.
10. Explain the importance of the copyright protection.
11. Explain objectives, responsibilities, scope, and functions of TGA.
12. Describe organizational structure, roles, and responsibilities of ANVISA.
13. Write the importance of contract research organization?
14. Explain regulations governing biosimilars.

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