Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - MAY-2018

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

Regulatory Affairs -II

Q.P. CODE: 5166

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. Describe in detail about parts of patents and filling of patents.
2. Explain continuous improvement and learning tools of TQM.
3. Describe the regulatory requirements for contract research organization.
4. Write the detail about regulation of Indian Pharmaceutical sector with respect to WHO.

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

5. Write a note on WIPO.
6. Write a note on MHRA.
7. Write the function of USFDA Guidelines.
8. Write a note on trademark protection in Regulatory guidelines.
9. Write a note on need of patent.
10. Discuss about post-market Data Regulation in Biosimilar.
11. Write the principle of TQM.
12. Write note on Biosimilar Regulation for clinical study.
13. Write a note on non-obviousness patent.
14. What is ANVISA.

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