Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - JAN-2019

Time: Three Hours **Max. Marks: 75 Marks**

International Regulatory Aspects of FNPCMB
Q.P. CODE: 5123

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. Write in detail about history and evolution of FFDCA of USA.
2. Discuss about organization and structure of EMA.
3. Elaborate in detail about drug regulatory approval process in Japan.
4. Write in detail about drug regulatory approval process in ASEAN region.

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

5. Write briefly about DMF system in US.
6. Write about national and mutual recognition procedures in EU.
7. Write a note on types of registration applications in China.
8. Approval process for IND in USA
9. Write a note on Eudralex directives for human medicines.
10. Write a note on drug approval in a south Asian country.
11. Write briefly about compliance of European pharmacopoeia.
12. Short note on post marketing surveillance in Japan.
13. Regulatory requirements for registration of drugs in Brazil
14. Write a note on marketing authorization transfers (MA).

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