Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - JUNE-2019

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

Biologicals Regulations

Q.P. CODE: 5146

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. Explain the Good Manufacturing Practice guidelines for biologics in India?
2. Write about the requirements for Plasma Master File (PMF) certification.
3. Describe the regulatory guidance for the development and approval of biosimilar products in the US.
4. What are the requirements for marketing authorization of biosimilar medicines in European Union?

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

5. Describe the principles for the development of similar biologics in India.
6. Differentiate between biological and generic drug.
7. Write a note on International Haemovigilance Network.
8. Give the labeling requirements for blood and blood products in US.
9. Discuss the stability and safety requirements for biologics in EU.
10. Explain the European Union marketing authorization for vaccines.
11. Write the regulatory requirements for blood components in India.
12. Write a note on Centre for Biologics Evaluation and Research (CBER).
13. Explain in brief about quality assessment of vaccines in US.
14. What are the post marketing data requirements for biologics in India?

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