Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - MAY-2019

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

Documentation and Regulatory Writing
Q.P. CODE: 5145

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 is product development report (PDR)? Discuss and significance of PDR. (6+4)
2. Define CTD and eCTD. Describe the modules of ICH-CTD format with granularity. (2+8)
3. What are audits? Explain the process of preparation and conduct of Audits. (2+4+4)
4. Discuss the Root cause analysis of a deviation. Describe corrective and preventive action (CAPA) process. (4+6)

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

5. Describe about Batch Manufacturing Record (BMR) and its calculations.
6. What is Drug Master File (DMF)? Discuss the types of DMFs.
7. Outline the contents and organization of dossiers.
8. Discuss the Non eCTD electronic submission (NeeS) format and its difference with CTD.
9. Differentiate internal, external, second party and external third party audits.
10. Describe the quality systems requirements of national good distribution practices.
11. Summarize the process and need in inspection of drug inspection of drug distribution channels.
12. Discuss the Post Approval Changes (SUPAC) process for an approved drug product.
13. Describe the process of post approval labeling changes.
14. Discuss the electronic submission process and validating the submission.

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