Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - MAY-2018

[Time: 3 Hours] [Max. Marks: 100]

Pharmaceutical Technology and Validation

(Revised Scheme 4)

Q.P. CODE: 9362

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

LONG ESSAY (Answer any TEN) **10 X 10 = 100 Marks**

1. Give brief overview of stability guidelines as per ICH Q1 and their brief scope of their application.
2. Define validation as per USFDA and classify their types.
3. How will you validate a Rapid Mixer Granulator?
4. Develop a process validation protocol of a solid oral dosage of your choice.
5. Explain the cleaning validation requirements of an equipment train for a total product changeover.
6. Write a note on calculations of limits in cleaning validation during the product changeover.
7. Explain SUPAC and list its advantages.
8. How do you develop dissolution method for an oral solid dosage form?
9. Explain the IQ, OQ and PQ of a multi station tablet compression machine.
10. How validation and verification differ in scope, explain in detail.
11. What are biowavers? List the condition on which biowavers are granted.
12. What is PMP? Why it is essential and how it is organized.

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