Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - JAN-2019

Time: Three Hours **Max. Marks: 100 Marks**

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. Explain the concept of evaluation of shelf life of a Pharmaceutical product as per ICH Q1E guideline.
2. Explain the evaluation procedure of Type I and Type II glass containers as per IP requirements.
3. Explain the general principles of product – packaging compatibility.
4. Explain the different approaches to collect the cleaning validation samples. Explain the concept of couponing for collecting cleaning validation samples.
5. What is revalidation? Explain the situations in which revalidation is essential?
6. What is IVIVC? Explain different levels of IVIVC correlations.
7. Explain the concept of SUPAC. How do you handle a SUPAC with a change in critical excipient for a scaled-up IR dosage form?
8. Explain with appropriate equations the F1 and F2 factors in dissolution testing.
9. Explain the tenets of GAMP and explain its applicability in pharmaceutical manufacturing.
10. How will you validate a double cone blender?
11. Discuss the factors affections dissolution and add a note on pharmacopoeial dissolution testing models.
12. Write a note on GAMP. What are the factors to be taken into account while using COTS?

* * * * *