Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination – Nov 2011

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

FORMULATION TECHNOLOGY AND VALIDATION

PAPER II

(RS 2 & RS 3)

Q.P. CODE: 9292

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

LONG ESSAY (Answer any TWO) **2 X 20 = 40 Marks**

1. Explain the validation of steam sterilization process
2. Write a note on evaluation of plastic containers and rubber closures for injectable preparations
3. What is stability testing? How is it performed and used for shelf life calculation

SHORT ESSAY (Answer any FIVE) **5 X 10 = 50 Marks**

4. Explain solubility enhancement by co solvent technique
5. Write a note on solution stability
6. Explain the evaluations of packing material for solid oral dosage form
7. Define transdermal drug delivery systems. What are their advantages? How are they evaluated
8. Write a note on organizing process validation
9. Describe the formulation and evaluation of chewable tablets

SHORT NOTES **2 X 5 = 10 Marks**

10. Draw a functional diagram of HVAC system for non-sterile dosage form manufacturing facility explaining each component
11. Explain "selectivity" in analytical method validation as per IUPAC recommendation 2001.

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