

# Rajiv Gandhi University of Health Sciences, Karnataka

## First Year M. Pharm Degree Examination – NOV 2016

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

### PREFORMULATION AND PRODUCTION MANAGEMENT (Revised Scheme 4)

**Q.P. CODE: 9337**

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

**LONG ESSAYS (Answer any Two)****2 x 20 = 40 Marks**

1. Discuss the salient features of CDSCO, USFDA and TGA.
2. What is validation? Explain its concepts, types, approaches and scope. Add a note on equipment qualification and cleaning validation.
3. Discuss in brief about various preformulation parameters. Outline the methods of enhancement of solubility?

**SHORT ESSAYS (Answer any FIVE)****5 x 10 = 50 Marks**

4. What are Heckle plots? Write their significance. Write briefly about formulation of mouth dissolving tablets.
5. What is optimization? Describe briefly about simplex method and factorial design in optimization.
6. Discuss various factors influencing the strength of tablets.
7. What is solid state drug stability? Discuss various strategies for prolonging shelf life of drugs.
8. Discuss about modern inventory management systems in pharma industry
9. With the help of neat layout explain the pilot plant for semisolids.

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

10. PAT
11. Industrial pollution and control measurements

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