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## 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

- Discuss the salient features of CDSCO, USFDA and TGA.
- 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

- What are Heckle plots? Write their significance. Write briefly about formulation of mouth dissolving tablets.
- What is optimization? Describe briefly about simplex method and factorial design in optimization.
- Discuss various factors influencing the strength of tablets.
- 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
- Industrial pollution and control measurements

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