

Rajiv Gandhi University of Health Sciences
First Year M.Pharm Degree Examination – May 2013

[Time: 3 Hours]

[Max. Marks: 100]

FORMULATION PRODUCTION MANAGEMENT**PAPER IV****(Revised Scheme 2)****Q.P. CODE : 9254**

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. What are the salient features and amendments of drugs and cosmetic act pertaining to manufacture and sale of drugs
2. Describe the influence of process patent era and product patent era on IPR environment in Indian pharmaceutical industry
3. Describe in detail regulatory issues involving effluent treatments and waste management

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

4. Discuss salient features of safety measures employed in pharmaceutical industry
5. Explain importance of production planning and forecasting in a pharmaceutical unit
6. Describe techniques of optimization applied in pharmaceutical formulation with examples
7. Discuss application of total quality management and its influence on productivity
8. Discuss the salient features of WHO GMP standards
9. Discuss the scale up techniques for tablets and liquid orals

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

10. Methods of costing of products and cost control
11. Discuss the ICH guidelines with respect to API

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