Rajiv Gandhi University of Health Sciences, Karnataka

First Year M. Pharm Degree Examination – Oct/Nov 2014

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

PRODUCTION MANAGEMENT AND REGULATORY AFFAIRS

(Revised Scheme 4)

Q.P. CODE: 9383

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. Elaborate the role of GMP in quality control and rational use of drug.
2. Discuss the objectives, composition and functions of CDSCO.
3. Discuss the elements of practice of production planning and inventory control management in pharmaceutical industry.

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

4. What is patent infringement? Describe with a case study.
5. Explain the drug regulatory affairs system in Australia.
6. Discuss the procedure for filling a Abbreviated New Drug Application.
7. What are ICH guidelines with respect to formulations pertaining to quality, safety and efficacy?
8. Discuss the issue and challenges in pharmaceutical packing.
9. Explain the importance and concept of lean manufacturing in Pharmaceutical Industry.

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

10. Investigational New drug application.
11. MHRA

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