Rajiv Gandhi University of Health Sciences

First Year M.Pharm Degree Examination – October 2010

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

GOOD MANUFACTURING AND LABORATORY PRACTICE

(Revised Scheme 2)

Q.P. CODE : 9204

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

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

1. Discuss the organizational set up of Quality Control unit, their responsibilities and various activities of the organization.
2. a) What is the design of the air control system adopted in the manufacturing units of antibiotics?
   b) Discuss the procedure to handle the complaints, its evaluation and rectification.
3. a) List out the ICH guidelines to qualify and quantify impurities in new drug substances.
   b) What are precautions to be taken in handling the cytotoxic substances in the manufacturing unit?

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

4. What are the measures to be considered before constructing a manufacturing unit?
5. List out the Good Laboratory Practice regulations to be followed in caring animals.
6. What do you mean by compliance of policy guidelines?
7. What is statutory certificate of suitability? Give its significance.
8. Discuss the various warehousing procedure for drug products
9. Write about validation equipments and documentation procedure to be followed in Industry.

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

10. What are the merits and short coming of using computer in maintaining Good Laboratory Practice and good Manufacturing practice?
11. International Standards Organization standards 14642-14644

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