Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - May 2016

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

Pharmaceutical Technology and Validation

(Revised Scheme 4)

Q.P. CODE: 9362

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 types of Compatibility Studies to be carried out during Preformulation and how is the Compatibility assessed? Explain in detail.
2. Classify Drug Substances as per BCS. Explain the approaches adopted to increase the Dissolution of Class III and Class IV drugs.
3. What are the types of Qualifications? Explain the types of Qualifications and Records there of for a Capsule Filling Machine.

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

4. Differentiate Stability Testing of a Drug Product and Drug Substance as per ICH Q2A (R1).
5. Write a note on SUPAC.
6. Explain the Quality Control Testing of Type II Glass Containers along with Acceptance criteria.
7. What are the Innovative Packaging Technologies available for Oral Dosage Forms? Explain.
8. Write a Representative MVP (Master Validation Plan) for a Tunnel Sterilizer.
9. Write a Typical Process Validation Protocol for "Diclofenac Sodium Gel".

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

10. Explain the terms "Clean in Place" and "Sterile in Place".
11. Write a note on GAMP Good Practice guidelines?

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