Register Number :

Name of the Candidate :

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ADVANCED DIPLOMA EXAMINATION, 2011

(VALIDATION TECHNIQUES FOR PHARMACEUTICAL INDUSTIRES)

(PAPER - III)

130. GOOD MANUFACTURING PRACTICE

December] [Time : 3 Hours

Maximum : 100 Marks

Answer any FIVE questions.
ALL questions carry equal marks.

1. Define documentation. Discuss its significnace in ensuring the control over the activities of pharma company. Explain the documentation procedure followed for standad test processes.

Turn Over

2. Write a note on :

   (a) Handling of returned goods.

   (b) Quality review.

   (c) Maintenance and sanitation for materials in warehouses.

   (d) Vendor audit.

3. Discuss the following in detail:

   (a) Contracture manufacture and analysis.

   (b) Good warehousing practices.

4. (a) Discuss the complaints and recall procedure followed in pharma company. Write its evaluation procedures.

   (b) Discuss the quality control documents maintained in a pharma company and write its significance.

5. Write in detail:

   (a) Computer system validation.

   (b) Proposed regulation of incharge control and SUPAC.

6. Give an account of

   (a) Recovered materials and reprocessing.

   (b) Premises and equipment required as per Schedule-M for solid dosage forms.