5. Write the validation steps involved in biotechnology products.

6. Mention the CGMP education involved in validation solid dosage form.

7. Mention in detail the factors involved in the validation of Transdermal process.

8. Discuss in detail the Gross contamination control and process microbial destruction in the validation of sterilization process.

Register Number :

Name of the Candidate :

7 0 8 8

ADVANCED DIPLOMA EXAMINATION, 2011

(VALIDATION TECHNIQUES FOR PHARMACEUTICAL INDUSTRIES)

(PAPER - I)

110. VALIDATION TECHNIQUE - I

December] [Time : 3 Hours

Maximum : 100 Marks

1. Write the regulatory considerations for the process validation procedure.

2. Discuss the product selection criteria, organizing for retrospective validation. Add a note on critial steps in restorspective validation.

3. Validation protocol for dry heat and Moist heat sterilization.

4. What are all the various approaches for verification, qualification and focus validation for medical devices?

Turn Over