



RO-5521

M. Pharm. (Part-II) Examination

May / June - 2010

822 - Validation, Regulatory Affairs & Product Development

Time : 3 Hours]

[Total Marks : 70

**Instructions :**

(1)

नीचे दृशावेक निशानीवाणी विगतो उत्तरवही पर अवश्य कपवी.  
Fillup strictly the details of signs on your answer book.

Name of the Examination :  
M. Pharm. (Part-2)

Name of the Subject :  
822-Validation, Regulatory Affairs & Product Development

Subject Code No. : 5 5 2 1 Section No. (1, 2,...): Nil

Seat No. :

Student's Signature

(2) Answer any five questions.

(3) All questions carry equal marks.

- 1 (a) Explain with an example 'Retrospective Process Validation'.  
(b) Why is a drug regulatory system required ? Which are the prominent regulatory bodies of the world ? Explain briefly the composition and functions of ICH.
- 2 (a) Explain the terms process capability and process qualification ? Describe the process characterization techniques.  
(b) Describe briefly the validation of a water supply system.
- 3 Describe the manufacturing process, in-process controls and the finished product specifications in manufacture of Aerosols.
- 4 Explain in detail the validation of a dry-heat sterilization process. Name the biological indicators used in the validation of various sterilization processes.

- 5 What is the need to conduct pilot plant studies ? What is scale-up and why is it required ? Discuss the parameters to be considered for scale-up of solid oral dosage forms.
  - 6 Describe in detail the validation of a tablet manufacturing process.
  - 7 Write a note on :
    - (a) Contract manufacturing
    - (b) Environment Protection Act.
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