



**R-5519**

**M. Pharm. (Part-II) Examination**

**May / June - 2010**

**422 : Pharmaceutical Technology Global Regulatory Requirement**

Time : Hours]

[Total Marks : 70

**Instructions :**

(1)

नीचे दशावेक निशानीवाणी विगतो उत्तरवडी पर अवश्य कभवी.  
Fillup strictly the details of signs on your answer book.

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

Name of the Subject :  
**422 : Pharmaceutical Technology Global Regulatory Requirement**

Subject Code No. : **5 5 1 9** Section No. (1, 2,.....): **Nil**

Seat No. :

Student's Signature

- (2) Attempt any **five** questions.  
(3) **All** questions carry **equal** marks.

- 1 Enumerate the packaging components. How do you evaluate the packaging components ?
- 2 Discuss various steps in regulatory Guidelines of ICH.
- 3 Discuss the sampling protocol of quality assurance and its importance.
- 4 How do you validate the granulation and blending process?
- 5 Brief introduction on scale up and post approval changes (SUPAC) for immediate release dispersible tablet formulations.

- 6 Discuss the drug approval process for abbreviated new drug application (ANDA).
- 7 Write notes on any **two** :
- (a) USFDA as a health regulatory agency
  - (b) Clinical study of good clinical practice
  - (c) Drug master file (DMF).
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