

**Subject Code: CEU13**

**M.Pharmacy - I Semester Regular/Supplementary Examinations, April - 2012**

**DRUG REGULATORY AFFAIRS  
(Pharmaceutics and Industrial Pharmacy)**

**Time: 3 Hours**

**Max Marks: 60**

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**Answer any FIVE questions. All questions carry EQUAL marks.**

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1. What are the regulatory requirements involved in the preformulation studies for parenteral products [12M]
2. a. Discuss the regulatory aspects of data requirement for new drug and excipients.  
b. Mention the regulatory requirements for packing materials [8M+4M]
3. a. Discuss the ICH guidelines of photo stability testing of dosage forms  
b. What are the current guidelines of biological products stability testing [8M+4M]
4. Discuss the biopharmaceutical considerations from the point of view of formulation, manufacturing process and stability [12M]
5. What are the current guidelines as per European Union for the conduct of bioavailability studies from the point of study design, statistical analysis and documentation [12M]
6. What are the guidelines to be followed in organizing preclinical studies for a new drug? Discuss the interpretation and presentation of data [12M]
7. Discuss the presentation, writing, application and procedure to be followed for patenting in India [12M]
8. Write a note on  
(i) importance of documentation in manufacturing  
(ii) Preformulation studies in liquid dosage forms  
(iii) Pharmacokinetic validation [4M+4M+4M]

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