

Subject Code: CEU13/R05

M. Pharm I Semester Supply Examinations, March, 2014

DRUG & REGULATORY AFFAIRS

**(Comm to Pharmaceutics, Industrial Pharmacy And Pharmaceutical
Technology)**

Time: 3 Hours

Max Marks: 60

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

1. Write about the regulatory requirements involved in the preformulation studies of various dosage forms as per the E.C, U.S and Indian regulatory authorities.
2. Explain the regulatory requirements as per E.C, U.S and Indian regulatory authorities for validation of manufacturing process and documentation for Active ingredients.
3. What are the regulatory guidelines for the materials used in packaging of pharmaceutical finished products? Explain how evaluation of closures will be done as per the guidelines.
4. (a) Write about the regulatory requirements for the stability testing of biological products and dosage forms in their final packaging.
(b) What are Intellectual Property rights?
5. Explain about different testing parameters and standards as per regulatory requirements of U.S and Indian regulatory authorities with respect to factors related to formulation and storage.
6. What are the current guidelines as per regulatory requirements of E.C, U.S and Indian regulatory authorities for the preclinical aspects of Biopharmaceutics?
7. What are Clinical trials? Explain the regulatory guidelines of the documentation, clinical study design with respect to various phases involved in clinical trials.
8. (a). Explain the procedure for obtaining and writing a patent as per Indian guidelines.
(b). Write about the regulatory affairs in respect of pharmacokinetic and toxicokinetic validation
