

Subject Code: CEU13/[R05]

M. Pharmacy I Semester Supplementary Examinations, April, 2015

**DRUG REGULATORY AFFAIRS
(Common to PC, IP and PCT)**

Time: 3 Hours

Max Marks: 60

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

- 1) Explain in detail regulatory requirements involved in formulation development of ocular preparations as per European and Indian regulatory authorities.
- 2) Write in detail manufacturing regulatory requirements as per united states and Indian regulatory authorities of the following
 - a) Process Validation of equipment
 - b) Test and evaluation of packaging materials
- 3) Explain in detail design of stability testing of bulk active drug substances as per United States regulatory authorities.
- 4) Write the major considerations to be followed manufacturing process of biopharmaceuticals as per European and Indian regulatory authorities.
- 5) Write in detail presentation documentation of preclinical aspects of drug to be followed as per United States regulatory authorities.
- 6) Explain in detail Phase I, Phase II, Phase III and Phase IV Studies innclinical trials as per European regulatory authorities.
- 7) Explain in detail Patent act and explain in detail how one can file application for international patent.
- 8) Write a short note on the following
 - a) Pharmacokinetic and Toxicokinetic validation
 - b) Elastometer test
 - c) ICH Guide lines
