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

****