**M. Pharm 1st Semester Examination**

**Subject- Regulatory Affairs (MPHI04T)**

**Full Marks- 75 Time – 3 hours**

**Answer any five questions:**

**1. Write notes on (10+5) (a) Discuss in detail about clinical-trial protocol.**

**(b) CTD and ECTD FORMAT.**

**2. Discuss about ICH guidelines i.e. Q,S,E,M (15)**

**3. Answer all. (10+5)**

**(a) HIPAA.**

**(b) ICH guidelines for MHRA.**

**4. Answer all. (7.5+7.5)**

**(a) Institutional Review Board.**

**(b) ICH guidelines for EV Region.**

**5. Answer all. (10+5)**

**(a) Post marketing surveillance**

**(b) Master formula Record**

**6. Discuss in detail about different points related to New Drug**

**application (15)**

**7. Answer all. (7.5+7.5)**

**(a) Hatch-Waxman Act and Amendments**

**(b) Drug Master file**