



Institute of Health Management Research, Jaipur

**Postgraduate Programme in Pharmaceutical Management
Batch V (2013-15)**

**Legal Environment for Pharmaceutical Business
(Term Exam)**

Duration: 3.00 (hrs).

Maximum Marks – 70

Attempt any 4 question, each carry equal (17.5) marks:

- Q1. Explain the patent filling process in Indian patent office with the help of flow chart?
- Q2. If company ABC pharmaceutical wants to conduct investigation of new chemical entity for oncology purpose in US than what are the procedures they have to follow for getting investigational approval?
- Q3. Discuss the various level of Documentation in following aspects:
- Product Development
 - Regulatory Affairs
 - Production
 - Marketing
- Q4. Discuss in detail about the objectives and roles of Trans Tasman Mutual Recognition Arrangement and Therapeutic Goods Administration (TGA)?
- Q5. Write short notes on: **(any 3)**
- a) Patent Search
 - b) Sale of goods act 1930
 - c) Patent cooperation treaty
 - d) ANDA
