



MBA Pharmaceutical Management

(2014-16)

**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?

Or

Discuss the various regulatory functions pertaining to pharmaceuticals market approval

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. Define patent infringement? And discuss various types of infringement? Also discuss under Hatch-Waxman act how ANDA (generic drug approval) is takes place?

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) IT act
- b) Consumer protection act
- c) Patent cooperation treaty
- d) ANDA
