

AT-1441

**M.B.A. Semester—III (New) Examination**  
**PHARMACEUTICAL REGULATORY ENVIRONMENT**  
**Paper—MBA/3506/PH**

Time : Three Hours]

[Maximum Marks : 70

**Note :—**(1) Attempt **ALL** questions.

(2) Figures to the right indicate full marks.

**SECTION—A**

1. (a) Explain in brief the rules of Import and Registration under the Drug and Cosmetic Rule, 1945. 14

**OR**

- (b) Explain in detail pharmaceutical drug regulations. 14

**SECTION—B**

2. (a) Explain provisions of Psychotropic and Narcotic Substances Act, 1985. 7  
(b) Explain how FDA will help manufacturer in drug recall with the help of suitable illustrations. 7

**OR**

- (c) Explain the role of government in manufacturing and distribution of controlled substances in Psychotropic and Narcotic Substance Act. 1985. 7  
(d) Explain in brief Consumer Protection Act. 7
3. (a) If a pharmaceutical company wants to register its product in foreign country. Explain the documents required. 7  
(b) Moon pharma developed a new molecule and wants to trade in India. Is it necessary to register for it ? Explain. 7

**OR**

- (c) Explain the documents required by a pharmaceutical company to register its product in India. 7  
(d) Explain the procedure for product registration in India. 7

**SECTION—C**

4. (a) State the harmonization of guidelines under ICH process in detail. 7  
(b) Explain the important regulation of USFDA. 7

**OR**

- (c) Explain in brief WHO and its role. 7  
(d) What is TGA ? Explain. 7

**SECTION—D**

5. The pharmaceutical industries are facing significant challenges to their existing business models because of expiring drug patents, declining risk tolerance of venture capitalists and other investors and increasing complexity in translational medicine. In response to these alternatives investment companies have emerged to bridge the biopharma funding gap by purchasing economic interests in drug royalty streams. Such purchases allow biopharma companies to monetize their intellectual property creating greater financial flexibility.  
(1) You are appointed as a management consultant. How will you explain the above case as per trade related intellectual property right ? 7  
(2) Analyze the case. 7