IIHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management
Batch-10 (2018-2020)
First Year

REGULATORY ENVIRNMENT IN PHARMACEUTICAL BUSINESS

Term Examination

Time - 3 Hours **MM-70**

The question paper contains 1 printed page.

Q. 1. Drug Price Control Order released by which agency in INDIA and how it controls the pricing of API and Formulations in Indian territory. **(15)**

Q.2. What do you mean by Biosimilars? Enlist the name of biosimilars which are launched in India. How biosimilars differs from generic medicine of conventional drugs. **(10)**

Q.3. Enlist the different schedules of Drugs and Cosmetic act 1940 with their titles. **(10)**

Q4. The generic manufacturer wants to get marketing authorization for his drug product Diclofenac+ Serratiopeptidase, kindly assist the applicant so that manufacturer get the marketing authorization under USFDA. **(12)**

Q5. In 2015, the Ebola hurts the west African countries, at the same time one of pharma company want to launch the vaccine for treating life threatening disease Ebola but this vaccine was held under clinical phase 1st, As a regulatory manager what will be you suggest to a company before they proceed to get the marketing authorization from the regulatory bodies? **(12)**

Q6. Write notes on : (any 4) **(11)**

1. ICH
2. DMF
3. CTD
4. IND
5. SNDA
6. SUPAC