Prof. Uday Kabaru

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

END SEMESTER EXAMINATION-2015

B.Pharm VI Semester

COURSE CODE: 10B11PY615 MAX. MARKS: 45

COURSE NAME: Drug Regulatory Affairs and IPR

COURSE CREDITS: 04 MAX. TIME: 3 HRS

Note: *All questions are compulsory. Carrying of mobile phone during examinations will be treated as case of unfair means.*

Section A

1. What is EMEA?
2. What is schedule X of Drugs & cosmetics act?
3. Define antitoxin What are the principles of sidelha?
4. Expand SFDA
5. Mention the types of yoga
6. Explain Naturopathy
7. What is the difference between Bioequivalence and bioavailability?
8. What is a medical device?
9. Define pharmacogenomics

Section B

1. State the Criteria for pharmaceutical equivalents.
2. What are the objectives of pharmacovigilance Programme of India (PvPI) for assuring drug safety?
3. Write about different parts and subparts of Schedule M of SDrugs & Cosmetics act 1940.
4. Write down the applications of GLP principles.

Section C

1. What are the regulatory aspects of GMP.
2. What can CDSCO do to protect the public when there are cGMP violations?
3. Briefly explain several medical systems that are followed in India.
4. Explain the different phases of clinical trials.