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JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT
MID SEMESTER EXAMINATION-2015
B.PHARM VI SEMESTER

COURSE CODE: 10B11PY615 MAX. MARKS: 30
COURSE NAME: Drug Regulatory Affairs and IPR
COURSE CREDITS: 4 MAX. TIME: 2HRS

Note: All questions are compulsory.

Section A (Marks: 6)

1. What does schedule M1 under GMP indicate?
2. What is CDSCO?
3. SFDA is associated with which country regulatory body?
4. What is Ayurveda?
5. Name the guideline developed by CDSCO with respect to import/manufacture and marketing approval of new drugs.
6. Explain naturopathy as a system of medicine?

Section B (Marks: 9)

1. If a manufacturer is not following GMP are the drugs safe for use? What can CDSCO do to protect against GMP violations? Explain.
2. Under what conditions a cosmetic shall be deemed misbranded or spurious?
3. Can a drug deemed to be bioequivalent be termed as therapeutic equivalent?

Section C (Marks: 15)

1. What are the regulatory aspects of GMP? How important are the problems associated with components such as filters, fan, humidifier, and cooling coil?
2. Can a bioequivalent study performed on new molecule not approved in India but approved in other countries? What are the requirements?
3. What are the functions undertaken by the central government to protect and promote public health in India.