

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER- III • EXAMINATION – WINTER 2016

Subject Code: 1931601**Date: 23/11/2016****Subject Name: Regulatory Affairs-II****Time: 10.30 am – 01.30 pm****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- | | | |
|-------------|--|-----------|
| Q.1 | (a) What is PCT? Describe the procedure for filing and processing international applications under PCT. | 06 |
| | (b) Discuss the recent developments relating to Bolar exemptions. | 05 |
| | (c) State the impact of Hatch-Waxman act on generic companies. | 05 |
| Q.2 | (a) How do regulatory aspects affect drug product design and manufacturing in a developing country? Explain giving suitable example. | 06 |
| | (b) Differentiate between INDA and ANDA. Describe various types of INDA. | 05 |
| | (c) Throw light on the recent amendments to Drugs and Cosmetic Act. | 05 |
| Q.3 | (a) What are the goals of NDA? Discuss the general requirements for filing NDA. | 06 |
| | (b) What is the procedure for contract manufacturing in India? | 05 |
| | (c) Write a detailed note on FDA guidelines for clinical trials. | 05 |
| Q.4 | (a) Describe briefly the procedure for obtaining license for manufacturing of drug substance. | 06 |
| | (b) Explain on documentation related to manufacturing. | 05 |
| | (c) Write a note on: WHO certification. | 05 |
| Q.5 | (a) Enumerate different parts of a patent and explain claims in detail. | 06 |
| | (b) Comment on the issues involved in export of drug products to US. | 05 |
| | (c) Write a note on quality and safety aspects for the cosmetic products. | 05 |
| Q. 6 | (a) Write a note on: Marketing and labor factors affecting foreign trade. | 06 |
| | (b) Describe BOP analysis in brief. | 05 |
| | (c) What are the policies of Indian Government in biotechnology patenting? | 05 |
| Q.7 | (a) Discuss the regulatory aspects and approval of herbal drugs in different countries. | 06 |
| | (b) Write a note on: Foreign exchange control. | 05 |
| | (c) Describe the importance of regulatory drug analysis. | 05 |
