

B. Pharm. Fifth Semester (C.B.S.) Examination
REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHT
Paper—6

Time : Three Hours]

[Maximum Marks : 80

- Note** :—(1) Question No. **1** is compulsory.
 (2) Attempt any **FOUR** questions out of remaining.
 (3) Draw neat labeled diagrams wherever necessary.
 (4) Assume suitable data wherever necessary.

1. Solve any **FIVE** of the following :— 4×5=20
 - (a) Describe industrial designs with suitable examples.
 - (b) Give the functions of regulatory affairs.
 - (c) What are trademarks ? Give their examples.
 - (d) Describe geographical indicators with suitable examples.
 - (e) Discuss in brief Hatch-Waxman Act.
 - (f) Explain the importance of Compulsory Licensing.
2. (a) Describe the requirements for filing of Abbreviated New Drug Application. 8
 (b) Give the types of Drug Master File. Add a note on contents of drug master file. 7
3. (a) Discuss the salient features of Patent Act, 1970. 8
 (b) Discuss in brief the Patent Co-operation Treaty. 7
4. (a) Discuss functions of USFDA. 8
 (b) Discuss in brief the patent application filing procedure in India. 7
5. Discuss the regulatory strategies during preclinical and clinical development phases. 15
6. (a) What are the objectives and functions of International Conference on Harmonization. 8
 (b) Describe the salient features of Indian Copyright Act. 7
7. Write short notes on any **THREE** :—
 - (a) Functions of Central Drug Standard Control Organization.
 - (b) Salient features of trade related Intellectual Property Rights Agreement.
 - (c) Functions of Therapeutic Goods Administration Agency of Australia.
 - (d) Contents of Investigational New Drug Application. 5×3=15