

B. Pharm. Fifth Semester (C.B.S.) Examination
REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHT
Paper-6 (5-T-6)

Time : Three Hours]

[Maximum Marks : 80

N.B. :— (1) Question No. **1** is compulsory.

- (2) Attempt any **FOUR** questions from the remaining.
- (3) Assume suitable data wherever necessary.
- (4) Discuss the reaction, mechanism wherever necessary.
- (5) Use of electronic calculator, excluding programmable calculator is permitted.

1. Solve any **FIVE** of the following :

- (a) Write short note on —Importance of Regulatory Affairs.
- (b) Describe functions of Regulatory Affairs.
- (c) Discuss in brief —Importance of IPR.
- (d) Describe — Copyrights.
- (e) Define patent, discuss importance of patent.
- (f) Write short note on — Criteria for granting a patent.
- (g) Write short note on — Trademarks. 5×4=20

2. (a) Write detail account on regulatory strategy during the pre-clinical development phase. 7

(b) Explain — Regulatory strategy during the clinical development phase. 8

3. Write detail account on drug regulatory authority and agencies in India and US. 15

4. (a) Explain — Content and format of Investigational New Drug Application. 7
(b) Discuss in detail — New Drug Application. 8
5. Write detail account on patent procedure, filing, search and licensing. 15
6. Discuss in detail Abbreviated New Drug Application (ANDA) and Types of Drug Master File (DMF). 15
7. Write short notes on (any **three**) :
- (a) Trade Related Intellectual Property Rights
- (b) Hatch —Waxman Act
- (c) Compulsory Licensing
- (d) World Trade Organisation (WTO). 5×3=15