

**First/Second/Third/Fourth/Fifth/Sixth
Semester Examination for the Degree of
Bachelor of Pharmacy**

**REGULATORY AFFAIRS AND INTELLECTUAL
PROPERTY RIGHT**

5 – T – 6

Time : Three Hours]

[Max. Marks : 80

- N. B. : (1) Question No. 1 is compulsory.
 (2) Attempt any four questions from the remaining.
 (3) Draw neat labelled diagram wherever necessary.
 (4) Discuss the reaction, mechanism wherever necessary.
 (5) Use of electronic calculator is permitted.
 (6) Assume suitable data wherever necessary.

1. Solve any **five** of the following :—

- (a) Define patent. Write the various criteria for granting the patent.
- (b) What is the role of Medicines and Health Care Regulatory Agency (MHRA).
- (c) Explain Hatch – Waxman Act.
- (d) Describe the term Intellectual property rights.
- (e) Mention the concept and format of an IND application.
- (f) Write short note on New drug application.
- (g) Describe Role of World Trade Organization (WTO).

5 × 4 = 20

2. (a) Describe the various requirements for filing ANDA
7
- (b) Discuss in detail the various International treaties and convention on IPR.
8
3. Explain the procedure for patent filling, searching and licensing.
15
4. (a) Write in detail on International Conference on Harmonisation (ICH).
7
- (b) Why the drug regulatory agencies are necessary ? Explain Therapeutic Goods Administration (TGA).
8
5. Define patent Act 1970, and patentability criteria and their importance.
15
6. Write the FDA guidelines, contents for New drug application.
15
7. Write short notes on (any **three**) :—
 - (a) Law related to biosimilars.
 - (b) General Agreement on Trade and Tariff (GATT).
 - (c) Indian Pharmacopoeia Commission (IPC).
 - (d) Medicines and Healthcare Regulatory Agency (MHRA).
5 × 3 = 15