

**TKN/KS/16-6998**

**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

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Contd.

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 filing, 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

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