NTK/KW/15/6998

Faculty of Pharmacy

B.Pharm. Fifth Semester (C.B.S.) Examination

REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHT

Paper—VI (5-T-6)

Time—Three Hours] [Full Marks—80

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

(2) Solve any **FOUR** questions from the remaining.

(3) Draw neat labeled 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 : 5×4=20

(1) Write the importance of Regulatory affairs.

(2) Give the scope and special feature of TRIPS.

(3) Describe Drug Master File (DMF) and its types.

(4) Write short on the Therapeutic Goods Administration (TGA).

(5) Write role of Medicines and Health Care Regulatory Agency (MHRA).

(6) Elaborate the term IPR and its significance.

(7) Write the importance of Regulatory affairs in Pharmacy Sector.

2. Why the drug Regulatory agencies are necessary ? Explain ICH and CDSCO. 15

3. (a) Explain Hatch Waxman Act. 8

(b) Justify "Regulatory affairs regulate the Marketing". 7

4. (a) Write the content of NDA. Discuss in detail the FDA guidelines for NDA application. 7

(b) Discuss in detail the various forms of IPR. 8

5. Define Investigation New Drug Administration (INDA). Give the basic component of INDA. 15

6. Give detailed Account on Patentability criteria and Patent amendment according to 2002 and 2005. 15

7. Write short notes on any **three** of the following : 5×3=15

(1) Compulsory Licensing

(2) Regulatory Strategy for post approval phase

(3) Patentable Subject Matter.

(4) USFDA.