KNT/KW/16/6569

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) Q. No. **1** is compulsory.

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

(3) Draw neat labeled diagram wherever necessary.

(4) Assume suitable data wherever necessary.

(5) Use of electronic calculator, excluding programmable calculator is permitted.

1. Solve any **FIVE** :—

   (a) Enlist various International Treaties and Conventions on IPR. Mention Global Drug Regulatory agencies.

   (b) Differentiate between — Generics and Biosimilars.

   (c) Give different types of Drug Master File (DMF).

   (d) Explain how Drug Regulatory Affairs department acts as a link between pharmaceutical industry and regulatory agency.

   (e) Give procedure of registering trade marks.

   (f) Write about role and responsibility of CDSCO. 5×4=20

2. (a) Give an account on Amendments to Indian Patent Act, 1970. 7

   (b) What do you mean by INDA ? What are the contents and format of IND application ? 8

3. (a) What are the various stages of filing patent through PCT ? Mention advantages of PCT. 7

   (b) Define New Drug. Give an account on various stages in filing New Drug Application. 8

4. (a) Describe the role and responsibilities of Drug regulatory agency. 7

   (b) Give an account on Hatch—Waxmann Act, 1984. Describe various requirements for filing Abbreviated New Drug Application (ANDA). 8

5. (a) Define the terms :—

(i) Patentability Criteria

(ii) Compulsory Licensing.

Give the scope and special features of TRIPS agreement. 8

(b) Give objectives and principles of Good Clinical Practice guideline (GCP). Add a note on Declaration of Helsinki. 7

6. (a) What do you mean by Common Technical Document (CTD) ? Give objectives and functions of ICH. 8

(b) Give an account on Intellectual Property Laws in India. Add a note on copyright. 7

7. Write short notes on (any **THREE**) :—

(a) Patent Infringement

(b) GATT and WTO

(c) Phases of Drug Development

(d) Good Manufacturing Practice guideline (GMP). 5×3=15