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DB-BP702T

Seat No. _____

B. Pharm. (Sem. VII) (CBCS) Examination

March – 2022

Industrial Pharmacy II

Time : **3** Hours] [Total Marks : **75**

Instruction : Figure to the right indicates full marks for the respective question.

1 Answer the following : **20**

(1) What is QbD?

(2) Why Non-clinical Trials are Important?

(3) Enlist the Quality Characteristics of a Regulatory Affairs Professionals.

(4) What is Quality Risk Management?

(5) Enumerate the functions of State Licensing Body of India.

(6) Give the full forms of SUPAC, COPP, BCIL, TBSE.

(7) Explain in brief the MoU and its Legal Issues.

(8) Enumerate the content of Clinical Trial Protocol.

(9) What are the Responsibilities of Regulatory Affairs Professional?

(10) Give the Name of Regulatory Authorities of the Countries: India, US, Brazil and Japan.

2 Answer the following : (Any **Two**) **20**

(1) Explain in brief about the WHO guideline on Technology Transfer. Also explain Granularity of Technology Transfer Process.

(2) Write a short note on NDA and its Approval Process.

(3) Describe in details about the Organizational Structure and Functions of Central Regulatory Authority of India.

3 Answer the following : (Any **Seven**) **35**

(1) Write a note on Change Control.

(2) Explain in brief about ISO 9000 series.

(3) Write a note on Scale up of Liquid Orals.

(4) Give the details of Documentation for Transfer of Technology (TOT).

(5) Describe in brief about the IND.

(6) Write a detailed note on Historical Overview of the Regulatory Affairs.

(7) Give a brief note on APCTD and TIFAC.

(8) Give a detailed note on COPP.

(9) Write a note on Drug Development Team.
