**Roll No……..** **Total No. of Printed Pages: [01]**
**Total No. of Questions: [13]**

**B. Pharmacy (Semester – 8th)**
**PHARMACEUTICAL REGULATORY SCIENCE**
**Subject Code: BP804ET**
**Paper ID: [17170143]**

**Time: 03 Hours** **Maximum Marks: 75**

**Instruction for candidates:**

1. Section A is compulsory. It consists of 10 parts of two marks each.
2. Section B consist of 9 questions of 5 marks each. The student has to attempt any 7 questions out of it.
3. Section C consist of 3 questions of 10 marks each. The student has to attempt any 2 questions.

**Section – A** **(2 marks each)**

Q1. Attempt the following:
a) Define regulatory documentation.
b) Enlist various stages of drug discovery.
c) Write about regulatory authorities of Canada and Japan.
d) Write the features of Purple book.
e) What do you mean by Federal Register?
f) What is informed consent process?
g) Write the role of CDSCO.
h) Write the role of WHO.
i) Give the features of Phase 3 clinical trials.
j) What is Abbreviated New Drug Application?

**Section – B** **(5 marks each)**

Q2. Discuss the concept of Innovator and generics.
Q3. Explain the Orange Book features.
Q4. Explain the approval process for implementing the changes to an approved NDA.
Q5. Explain the Common Technical Document.
Q6. Explain the informed consent process & procedure involved in clinical trials.
Q7. Explain the Drug Master File.
Q8. Write the composition and functions of Institutional Review Board.
Q9. Discuss the significance of Pharmacovigilance and safety monitoring in clinical trials.
Q10. Discuss Code of Federal Regulatory.

**Section – C** **(10 marks each)**

Q11. Write a detailed note on Approval processes and timelines involved in Investigational New Drug (IND) application
Q12. Explain the design in developing clinical trial protocols.
Q13. Explain the procedure for export of pharmaceutical products in overseas market.