

**Roll No.**

**Total No. of Pages : 02**

**Total No. of Questions : 13**

**B.Pharmacy (Sem.-8)**

## PHARMACEUTICAL REGULATORY SCIENCE

**Subject Code : BP804ET**

**M.Code : 79767**

**Date of Examination : 06-01-2023**

**Time : 3 Hrs.**

**Max. Marks : 75**

**INSTRUCTIONS TO CANDIDATES :**

1. **SECTION-A is COMPULSORY** consisting of **TEN** questions carrying **TWO** marks each.
2. **SECTION-B** contains **THREE** questions carrying **TEN** marks each and student has to attempt any **TWO** questions.
3. **SECTION-C** contains **NINE** questions carrying **FIVE** marks each and student has to attempt any **SEVEN** questions.

## SECTION-A

1. **Write briefly :**
- a) What is meant by Phase-I studies?
  - b) What is a generic product?
  - c) What is a proprietary product?
  - d) Name the regulatory authorities of India and USA.
  - e) Mention the different types of DMFs.
  - f) What is the purpose of micro dosing studies?
  - g) What is meant by '*exclusion criteria*' in clinical trials?
  - h) What is '*orange book*'?
  - i) What is meant by '*informed consent*'?
  - j) What is meant by '*double blind trial*'?

## SECTION-B

2. Discuss the Indian regulations for export and import of pharmaceuticals.
3. Discuss the '*inclusion*' and '*exclusion*' criteria for anti-diabetic drug clinical trial.
4. What is ANDA? Discuss the regulatory requirements for filing ANDA.

## SECTION-C

5. Differentiate between NCE and Lead Molecule.
6. Differentiate between IND and ANDA.
7. Outline the process of developing a generic product.
8. What is the constitution and functions of Institutional Ethics Committee?
9. What is the constitution and purpose of IRB?
10. Comment on the process of obtaining consent of a volunteer for clinical trial.
11. Briefly discuss the process and modes of pharmacovigilance.
12. Comment on provisions contained in Schedule - Y.
13. Write a note on eCTD.

**NOTE : Disclosure of Identity by writing Mobile No. or Marking of passing request on any paper of Answer Sheet will lead to UMC against the Student.**