**Roll No.** | | | | | | | | | | | | **Total No. of Pages : 02**

**Total No. of Questions : 07**

**M.Sc. (Clinical Research) (Sem.-2)**

# INTERNATIONAL REGULATORY AFFAIRS

**Subject Code : UC-MSCR212-19**

**M.Code : 79907**

**Date of Examination : 04-01-2023**

**Time : 2 Hrs.** **Max. Marks : 35**

**INSTRUCTIONS TO CANDIDATES :**

1. **SECTION-A is COMPULSORY consisting of FIVE questions carrying ONE marks each.**
2. **SECTION-B contains THREE questions carrying FIVE marks each and students have to attempt any TWO questions.**
3. **SECTION-C contains THREE questions carrying TEN marks each and students have to attempt any TWO questions.**

## SECTION-A

**1. Write briefly:**

a. OEEC which was established in 1948 and OECD grew out of OEEC. Which year OCED took over OEEC?

b. ANVISA stands for_____and dealt as regulatory agency for which country_____.

c. Who is the chief executive of PMDA and to which country does it belongs?

d. What is GCC and does it work specifically in which region of the world?

e. What is HIPAA Security rule?

## SECTION-B

2. Write a short note on the working of the Brazilian Health Surveillance Agency.

3. How the Japanese Drug regulatory system PMDA is different from the Australian Regulatory System TGA?

4. How does New Zealand-based regulatory agency MedSafe control the approval, import, and usage of medical devices?

## SECTION-C

5. Write a detailed note on Central Drug Registration governed by Gulf Cooperation Council.

6. Write a detailed note on the measures taken upon serious effect occurred due to ADR caused by any drug or medical devices under the Japanese regulatory agency PMDA.

7. Write a detailed note including origin, timeline, organizational structure, and procedure of new product registration under South African Health Products Regulatory Authority.

**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**.