

## **UNIT-V: Indian Regulatory Requirements**

### **Elaborate Questions (10 Marks):**

1. Discuss the **organization and responsibilities of the Central Drug Standard Control Organization (CDSCO)** and State Licensing Authorities [4, 9].
2. Explain the **Certificate of Pharmaceutical Product (COPP)**. Discuss its significance and the procedure to obtain it [4, 8, 9, 15].

### **Notes Questions (5 Marks):**

1. Write a note on the **Central Drug Standard Control Organization (CDSCO)** [4, 9, 11, 15].
2. Explain the **responsibilities of State Licensing Authorities** [4, 13].
3. Write a short note on **post-marketing surveillance** [7]. (While not explicitly in BP702T Unit V, it's a related concept often covered with regulatory affairs).

### **Short Answer Questions (2 Marks):**

1. What is **CDSCO**? [15]
2. What is **COPP**? [8, 15]
3. What is a **State Licensing Authority**? [15]