

**Maharshi Karve Stree Shikshan Samstha's**

**Smt. Hiraben Nanavati Institute of Management & Research for Women**

**INTERNAL EXAMINATION – Sem II – ( Jan- July 2026)**

**SUBJECT – Regulatory laws in Indian Pharmaceutical & healthcare Industry    SUBJECT CODE – PHM 653**

**Date : 08-05-2026**

**Pattern : 2024**

**Duration : 150 min**

**Max Marks : 50**

**Instructions for students :**

- *Marks are indicated for each question.*
  - *Handwriting should be eligible for evaluation.*
  - *Marks will be given for quality, not quantity.*
- 

**Q.1]** Answer the following questions

( 5 Questions – 2 Marks Each)

(10 Marks)

- Define a valid contract and list its essential elements.
- What is free consent in contract law?
- List any four medico-legal responsibilities of hospitals.
- Name any two laws related to drugs and pharmacy in India.
- Match the following:

Column A

Column B

1. Pharmacy Act

a. Consumer rights protection

2. Consumer Protection Act

b. Regulation of pharmacists

3. IT Act, 2000

c. Data security

4. NDPS Act

d. Control of narcotic drugs

**Q.2]** Attempt any Two ( 5 Marks Each )

(10 Marks)

- Compare void agreements and contingent contracts.
- Summarize the provisions of the Drugs and Cosmetics Act, 1940.
- Contrast Consumer Protection Act and IT Act, 2000 in healthcare context.

**Q.3]** Attempt any One ( 10 Marks )

(10 Marks)

- Explain the essentials of a valid contract, including offer, acceptance, consideration, capacity, and free consent.
- Demonstrate the medico-legal responsibilities of hospitals with suitable examples and cases.

**Q.4]** Attempt any One ( 10 Marks )

*(10 Marks)*

a) A patient files a complaint against a hospital for negligence and deficiency in service. Analyse the case under the Consumer Protection Act, and explain the role of consumer dispute redressal agencies.

OR

b) A hospital is implementing electronic health records (EHR). Analyse the legal and data privacy issues involved under IT Act, 2000 and GDPR, and suggest compliance measures.

**Q.5]** Answer the following (any one)

*(10 Marks)*

a) Design a compliance framework for a hospital to ensure adherence to laws related to contracts, drugs, consumer protection, and data privacy.

OR

b) Imagine you are a hospital administrator. Create a policy for handling medico-legal cases and patient data protection, ensuring legal compliance and ethical standards.