

Total No. of Questions : 5]

SEAT No. :

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S.Y.M.B.A.

**PHM 653 MJ SC PHM-02 : REGULATORY LAWS IN INDIAN
PHARMACEUTICAL & HEALTHCARE INDUSTRY
(2024 Pattern) (Semester - IV)**

Time : 2½ Hours]

[Max. Marks : 50

Instructions to the candidates:

- 1) *All questions are compulsory.*
- 2) *Each question has internal options.*
- 3) *Each question carries equal marks.*

Q1) Solve any five of the following:

[10]

- a) State any two essentials of a contract.
- b) Define offer and acceptance in contract law.
- c) State features of contingent contracts.
- d) What is cyber security in healthcare?
- e) Define Indian Medical Council Act, 1956.
- f) State any two health data privacy requirements under the Information Technology Act, 2000.
- g) What is GDPR?
- h) Mention objectives of the Drugs and Cosmetics Act, 1940.

Q2) Attempt any two out of three from the following:

[10]

- a) Explain the essentials of a valid contract with suitable examples.
- b) Discuss medico-legal problems related to hospital administration.
- c) Explain the structure and functions of Consumer Disputes Redressal Agencies.

Q3) Answer 3 (a) or 3 (b)

[10]

- a) Discuss the provisions and significance of the Narcotic Drugs and Psychotropic Substances Act, 1985 in controlling drug abuse and illegal trafficking.
- b) Explain the Consumer Protection Act, 2019 in hospitals and discuss its implications for healthcare professionals with suitable examples.

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Q4) Answer 4 (a) or 4 (b)

[10]

- a) Discuss the importance of Electronic Health Records (EHR) guidelines and measures required to ensure compliance in healthcare organizations.
- b) Explain the provisions related to blood bank regulation under the Drugs and Cosmetics Act, 1940.

Q5) Answer 5 (a) or 5 (b)

[10]

- a) Explain the impact of GDPR on Indian pharmaceutical and healthcare industries with suitable examples.
- b) Discuss the role of the Indian Medical Council Act, 1956 in regulating medical education and professional ethics in India.

