

Total No. of Questions : 5]

SEAT No. :

PF-12128

[Total No. of Pages : 2

[6648]-830

M.B.A.

**SEPHM-11 : REGULATORY AFFAIRS IN
PHARMACEUTICALS**

(2024 Pattern) (Semester - IV)

Time : 2½ Hours]

[Max. Marks : 50

Instructions to the candidates:

- 1) All questions are compulsory.
- 2) Each question carries equal marks.

Q1) Solve any five :

[5 × 2 = 10]

- a) Define Drug Regulatory Affairs.
- b) What is the role of CDSCO in India?
- c) Define Abbreviated New Drug Application (ANDA).
- d) What is the purpose of the Common Technical Document (CTD)?
- e) Mention any two objectives of regulatory inspections.
- f) What is meant by Biologics License Application (BLA)?
- g) Mention any two post-marketing requirements for drugs.
- h) What is meant by drug recall?

Q2) Solve any two :

[2 × 5 = 10]

- a) Discuss the importance of GMP compliance in pharmaceutical manufacturing.
- b) Discuss the challenges faced during the drug approval process.
- c) Discuss the role of drug regulatory professionals in the pharmaceutical industry.

P.T.O.

Q3) Answer any one :

[1 × 10 = 10]

- a) Discuss the impact of TRIPS agreement on the pharmaceutical industry.
- b) Discuss the regulatory framework of the European Union for drug approval and marketing.

Q4) Answer any one :

[1 × 10 = 10]

- a) Explain the role of Digital Health in modern healthcare systems and its regulatory considerations.
- b) Discuss the role of biosimilars in modern healthcare and related regulatory issues.

Q5) Answer any one :

[1 × 10 = 10]

- a) Explain the different types of Intellectual Property Rights and their relevance in pharmaceuticals.
- b) Discuss the procedure for patent filing in India in detail.
