INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmaceutics)

Backlog Examination (2025 Pattern) April/ May – 2026 - Semester – I

Subject Name: Regulatory Affairs **Max. Marks: 75**
Subject Code: MPH104T **Time: 3 Hours**

Instructions

- All Questions Are Compulsory. Write two sections on separate answer sheets
- Neat diagram must be drawn wherever necessary
- Figures to the right indicate full marks

Section : I

Q.1 Solve any ONE from the following **15 Marks**

a. Differentiate between NDA and IND. Design a regulatory roadmap for a drug manufacturer aiming to obtain NDA approval for new drug product in the United States.

b. Evaluate the role and importance of the Drug Master File (DMF) in the drug approval process in the United States. How does it ensure confidentiality and regulatory compliance?

Q.2 Solve any FOUR from the following **20 Marks**

a. Explain the Code of Federal Regulations (CFR) and its role in pharmaceutical compliance.

b. What is the role of Contract Research Organizations (CROs) in bioavailability (BA) and bioequivalence (BE) studies?

c. Discuss various classes of medical devices.

d. Comment on- Hatch-Waxman Act and its significance.

e. Explain the importance and contents of Master Formula Record (MFR).

f. Elaborate on distribution records.

Section : II

Q.3 Solve any ONE from the following **15 Marks**

a. Illustrate in detail the design and significance of Informed Consent.

b. Discuss in detail marketing authorization of drugs under EU.

Q.4 Solve any TWO from the following **15 Marks**

a. Illustrate the importance of IMPD.

b. Discuss eCTD and its advantages..

c. Define critical quality attributes (CQAs) with an example.

d. Explain the term Quality Target Product Profile (QTPP) and its relevance in ICH Q8 Pharmaceutical Development.

Q.5 Solve any TWO from the following **10 Marks**

a. Discuss the SUPAC guidelines for changes in the manufacturing process.

b. Discuss the identification, qualification, and control of impurities in new drug substances (Q3A) and products (Q3B).

c. Describe the key elements of Pharmaceutical Development as per ICH Q8.

d. Describe the procedure for drug approval in Australia.

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