

# INDIRA UNIVERSITY, PUNE

## SCHOOL OF PHARMACY- M.PHARM (Pharmaceutics)

Term End Examination (2025 Pattern) December – 2025 - Semester – I

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**Subject Name: Regulatory Affairs**  
**Subject Code: MPH104T**

**Max. Marks: 75**  
**Time: 3 Hours**

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### 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
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### Section : I

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

- a Differentiate between NDA and ANDA. Design a regulatory roadmap for a foreign generic drug manufacturer aiming to obtain ANDA approval in the US. Include preclinical, clinical, and post-approval activities.
- b Discuss the Hatch-Waxman Act and its amendments. How has it impacted the balance between innovation and access to pharmaceutical generics? Provide examples of exclusivity and patent challenges.

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

- a Define Master Formula Record (MFR) and state its importance in the pharmaceutical industry.
- b Discuss regulatory requirement for the approval of biologics.
- c Define the term 'Scale-Up and Post-Approval Changes (SUPAC)' and discuss SUPAC guidelines for change in manufacturing site.
- d Discuss post marketing surveillance with respect to clinical trials.
- e Discuss regulatory requirement for the approval of ANDA.
- f Explain the Code of Federal Regulations (CFR) and its contents.

### Section : II

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

- a Illustrate in detail the formation and working of institutional review board.
- b Discuss in detail CTD along with the advantages of eCTD.

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

**15 Marks**

- a** Illustrate salient features of clinical trial protocol.
- b** Discuss the contents of the investigator's brochure.
- c** Discuss the classification of residual solvents as per ICH Q3C with appropriate examples.
- d** Discuss the role of each element of the PQS in ensuring product quality as per ICH Q10.

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

**10 Marks**

- a** Discuss the process and importance of pharmacovigilance in safety monitoring.
- b** Discuss the composition of institutional ethics committee.
- c** Discuss the types of medical devices.
- d** Define ROW and discuss the requirements of drug approval in ASEAN countries.

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