

**INDIRA UNIVERSITY, PUNE**  
**SCHOOL OF PHARMACY-M.PHARM (PQA)**

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

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**Subject Name: Product Development & Technology Transfer**  
**Subject Code: MQA104T**

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

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**Instructions**

- All questions are compulsory.
  - Figures to the right indicate full marks.
  - Attempt two sections on separate answer sheets.
  - Illustrate your answers with neat figures and diagrams.
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**Section : I**

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

- a. Explain the concept of pre-formulation studies and discuss various pre-formulation parameters.
- b. Discuss the concept and significance of pilot plant scale up and give details of large scale manufacturing of semisolids.

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

- a. What is product Registration? Discuss registration of finished formulations in India as per CDSCO.
- b. Demonstrate the key design considerations of a pilot plant and their role in facilitating efficient scale-up of pharmaceutical products.
- c. Write a note on BACPAC.
- d. Illustrate the opportunities and challenges in the development of new era drug products in pharmaceutical practice.
- e. Write a note on Supplemental New Drug Application (SNDA). Explain when and why an SNDA is filed by a pharmaceutical company giving suitable examples.
- f. Outline and briefly discuss the clinical research process step-by-step. Compare the objectives and outputs of all phases.

**Section : II**

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

- a. Outline the different phases of technology transfer and explain their significance.

- b. Define and state importance of solubility in the context of drugs. Mention various methods to enhance solubility and discuss two methods in depth.

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

**15 Marks**

- a. Compare qualitative and quantitative technology transfer models in pharmaceutical manufacturing and evaluate their significance in successful technology transfer.
- b. What is aseptic packaging system? What are its advantages? Write about methods of sterilization of aseptic packaging materials.
- c. Examine the roles of key members in a pharmaceutical technology transfer team.
- d. Classify medical devices giving suitable examples. Write about Medical device packaging.

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

**10 Marks**

- a. Describe the types of glass used in pharmaceutical packaging. List and explain quality control tests performed on glass containers.
- b. What is stability testing of pharmaceuticals products? Discuss about the accelerated stability testing.
- c. Explain how polymorphism affects the physicochemical and biopharmaceutical properties of a drug. Analyse how DSC thermograms can help distinguish among different polymorphs with suitable examples.
- d. Examine the importance of technology transfer in pharmaceutical manufacturing. Add a note on Development report.