INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmaceutical Quality Assurance)

Term End Examination (2025 Pattern) April- May – 2026- Semester – II

Course Name: Pharmaceutical Manufacturing Technology **Max. Marks: 75**
Course Code: MQA204T **Time: 3:00 Hrs.**

Instructions

- All Questions are Compulsory. Write two sections on separate answersheets.
- 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. Describe process layout and product layout with neat, labelled diagrams. Explain factors affecting pharmaceutical plant layout. Discuss special provisions required in pharmaceutical plant design.

b. Discuss the key elements of aseptic processing. Draw the manufacturing flowchart for sterile suspensions. Elaborate in-process quality control tests for sterile suspensions.

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

a. Explain different production systems used in pharmaceutical industries.

b. Give an overview of area planning and environmental control for sterile product manufacturing.

c. Describe the Cleaning in Place (CIP) system with emphasis on its operational cycle. key components, and significance in pharmaceutical equipment cleaning.

d. Compile and elaborate In process quality control tests for Large volume parenteral.

e. Outline the regulatory licences required for establishing a pharmaceutical manufacturing facility.

f. Describe the lyophilization process with a neat labelled diagram of a lyophilizer. Discuss its significance in improving stability of pharmaceutical products.

Section : II

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

a. Explain the concept and importance of granulation technology in pharmaceutical manufacturing. Describe the wet and dry granulation processes. Discuss the principle, construction, and working of the following equipment used in granulation: a) Rapid Mixer Granulator b) Rota Granulator c) Roller Compactor.

b. Explain the concept of Quality by Design (QbD). Define QTPP, CQA, CPP, and CMA. Discuss the role of Design of Experiments (DoE), risk assessment, and Process Analytical Technology (PAT) in ensuring product quality.

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

a. Explain the fluidized bed coating process, equipment and its pharmaceutical applications.

b. Discuss the concept and importance of transit worthiness in pharmaceutical packaging. Explain the tests used to evaluate transit worthiness.

c. Briefly explain the concept of Analytical QbD. Discuss any four key elements of AQbD that contribute to product quality.

d. Describe bubble packs, blister packs and shrink packaging used in pharmaceutical packaging. Add a note on drug plastic interaction.

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

a. Discuss the common defects encountered during tablet coating with their causes.

b. Enumerate the quality control tests for pharmaceutical closures and explain their significance.

c. Explain Ishikawa diagram and Failure Mode and Effects Analysis (FMEA) as risk assessment tools used in Quality by Design (QbD).

d. Enumerate the common and specific quality control tests for strip and blister packaging.