INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- M. PHARM (PQA)

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

Subject Name: Quality Control And Quality Assurance **Max. Marks: 75**
Subject Code: MQA103T **Time: 3 Hours**

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 Explain the concept of Quality Assurance in the pharmaceutical industry. Give a brief account of the responsibilities of the Quality Control and Quality Assurance departments.

b Elaborate and discuss in detail cGMP guidelines by USFDA concerning pharmaceutical organization, staff roles, training, and facility design? Justify their importance in maintaining product quality, safety, and regulatory compliance.

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

a Describe how Schedule M ensures GMP compliance in equipment and documentation.

b What is the role of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in international regulatory harmonization?

c Outline the significance of control on animal house facilities under CCSEA compliance.

d Discuss the FPQC for creams.

e Discuss the critical aspects of report writing and documentation practices followed under Good Laboratory Practices

f Elaborate about CDER and CBER

Section : II

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

a Describe the In-Process Quality Control and finished product quality control tests for tablets as per pharmacopoeial standards.

b Discuss the importance of control parameters during manufacturing operations in the pharmaceutical industry to ensure product quality. Elaborate aseptic process control in detail.

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

a Elaborate CTD & eCTD for regulatory submissions.

b Comment on regulated and non-regulated markets in the pharmaceutical sector?

C Explain the concept of process deviation and describe the procedure for charge-in of components in the pharmaceutical industry.

d Explain the significance of monitoring OOT and OOS results in pharmaceutical manufacturing. How do they impact product quality and regulatory compliance?

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

a Discuss how to write Standard Operating Procedures.

b Give detailed account on expiry date calculation and calculation of yields.

c Discuss the Batch Manufacturing Record and its importance.

d Elaborate IPQC tests for Capsule formulation.