

INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- M. PHARM (PQA)

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

Subject Name: Quality Management System
Subject Code: MQA102T

Max. Marks:75
Time: 3:00Hrs.

Instructions

- All questions are compulsory
 - Give working notes wherever required.
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Section : I

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

- Explain in detail Models of cost of quality and add note on preventing cost of quality.
- What is accreditation? Explain in detail NABL certification and add note on ISO 14001:2004 certification.

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

- Discuss in detail the dimensions of quality.
- Discuss statistical control charts in detail.
- Explain CAPA in pharma industry.
- Describe batch review and batch release in pharma industry.
- Write a short note on Quality Management system.
- Discuss risk ranking and filtering according to ICH Q9 guideline

Section : II

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

- Elaborate the term six system inspection model.
- Summarize ICH guidelines for stability testing drug substances and drug products.

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

- Write a short note on CFR-21
- Describe requirements of customers.
- Write a short note on Vendor qualifications

d Discuss the process of benchmarking with suitable example

Q.5 Solve any TWO from the following -

10 Marks

a Write a short note on Annual Product Reviews

b Explain Measuring process control through SPC

c Discuss the term vision and mission.

d Discuss the term drug stability.