

FACULTY OF PHARMACY

B. Pharmacy VI-Semester (PCI) (Main) Examination, December 2020

Subject: Quality Assurance

Time: 2 Hours

Max. Marks: 75

PART – A

Note: Answer any Seven questions.

(7 x3=21 Marks)

1. Define TQM
2. Give difference between Quality Assurance & Quality Control.
3. State the purpose of ICH.
4. Name Quality Control tests for glass containers.
5. Name different parameters of Analytical method validation.
6. Name any four responsibilities of Quality control people.
7. Mention classification of Recall.
8. What is qualification and validation .
9. Enlist the scope for validation.
10. Give the principles of NABL accreditation.

PART – B

Note: Answer One question.

(1 x14=14 Marks)

- 11.a) Define Quality by Design.
b) Write in detail note on QbD.
12. Write a short note on plant layout with example.
13. Explain Good Warehousing practices.

PART - C

Note: Answer any Five questions.

(5x8=40 Marks)

14. Write in detail Equipment Validation.
15. Draw cause and effect diagram for tablet manufacturing process.
16. Write in detail parameters to be checked in Quality Audit.
17. Write short note on ISO 9000.
18. Explain in short Good Laboratory practices.
19. Explain steps involved in complain handling.
20. Explain the term “validation Master Plan”.
21. What is forced degradation stability study? Explain in short.
22. Write a note on Quality Management System.