Faculty of Pharmacy
End Semester Examination May 2025
PY3CO28 Pharmaceutical Quality Assurance

| Programme | : | B. Pharm. | Branch/Specialisation | : | - |
| Duration | : | 3 hours | Maximum Marks | : | 75 |

Note: *All questions are compulsory. Internal choices, if any, are indicated. Assume suitable data if necessary. Notations and symbols have their usual meaning.*

Section 1 (Answer all question(s))	Marks	CO	BL

Q1. Give responsibilities of QA department.   2   1   1

Rubric	Marks
Any four responsibilities of QA department -2M	2

Q2. Enlist elements of TQM.   2   1   1

Rubric	Marks
Elements of TQM -2M	2

Q3. What is JD?   2   2   1

Rubric	Marks
Job Description -2M	2

Q4. What is FIFO?   2   2   1

Rubric	Marks
First In First Out -2M	2

Q5. Write objectives of GLP.   2   3   1

Rubric	Marks
Objectives of GLP.	2

Q6. Enlist packing materials with examples.   2   3   1

Rubric	Marks
1,2,3 packing materials with examples	2

Q7. Define document.   2   4   1

Rubric	Marks
Definition of document	2

Q8. Enlist types of complaint.   2   4   1

Rubric	Marks
Types of complaint -2M	2

Q9. Define validation.   2   5   1

Rubric	Marks
Definition of Validation-2M	2

Q10. Enlist inventory control models.   2   5   1

Rubric	Marks
Economic order quantity (EOQ), Always Better Control (ABC) Analysis, VED Analysis, FSN Analysis	2

Section 2 (Answer any 2 question(s))   Marks CO BL
Q11. Write a note on elements of QbD & tools for risk assessment.   10   1   1

Rubric	Marks
Elements of QbD – 5 M	5
Tools for risk assessment -5M	5

Q12. Write a detailed note on equipment qualification & maintenance for equipment.   10   2   1

Rubric	Marks
Equipment qualification -5M	5
Maintenance for equipment -5M	5

Q13. Enlist principles & elements of TQM. Write a note on construction & plant layout.   10   1   1

Rubric	Marks
(a)Principles of TQM	2.5
(a)Elements of TQM	2.5
(b)Construction	2.5
(b)Plant layout	2.5

Section 3 (Answer any 2 question(s))   Marks CO BL
Q14. Explain different types of quality control test for glass containers.   5   3   1

Rubric	Marks
Quality control test for glass containers – any five in detailed	5

Q15. Write general principles for GLP.   5   3   1

Rubric	Marks
General principles for GLP – any 5 principles in detailed	5

Q16. Explain different types of quality control test for rubber closures.   5   3   1

Rubric	Marks
Quality control test for rubber closures –any five in detailed	5

Section 4 (Answer any 2 question(s))   Marks CO BL

Q17. Elaborate recalling of goods.   5   4   1

Rubric	Marks
Recalling of goods procedure	5

Q18. Write a note on batch manufacturing record.   5   4   1

Rubric	Marks
Batch Manufacturing Record – Contents of BMR	5

Q19. Write a note on the standard operating procedure.   5   4   1

Rubric	Marks
Standard Operating Procedure – Contents of SOP	5

Section 5 (Answer all question(s))

Marks CO BL

Q20. Write a note on process validation.   5   5   1

Rubric	Marks
Definition of Process validation	2
Types of process validation	3

Q21. Write a note on good warehousing practice.   5   5   1

Rubric	Marks
Good warehousing practice	5

Q22. Write a note on analytical method validation.   5   5   1

Rubric	Marks
Analytical method validation explanation in detail. Principles of AMV.	5

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