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Printed Page:-3 **Subject Code:- AMTBT0112**

Roll. No:

NOIDA INSTITUTE OF ENGINEERING AND TECHNOLOGY, GREATER NOIDA
(An Autonomous Institute Affiliated to AKTU, Lucknow)
M.Tech
SEM: I - THEORY EXAMINATION (2025 - 2026)
Subject: Quality Assurance and Quality Control

Time: 3 Hours **Max. Marks: 70**

General Instructions:

IMP: *Verify that you have received the question paper with the correct course, code, branch etc.*

1. *This Question paper comprises of* ***three Sections -A, B, & C.*** *It consists of Multiple Choice Questions (MCQ's) & Subjective type questions.*

2. *Maximum marks for each question are indicated on right -hand side of each question.*

3. *Illustrate your answers with neat sketches wherever necessary.*

4. *Assume suitable data if necessary.*

5. *Preferably, write the answers in sequential order.*

6. *No sheet should be left blank. Any written material after a blank sheet will not be evaluated/checked.*

SECTION-A 15

1. Attempt all parts:-

1-a. Quality Assurance mainly focuses on (CO1, K1) 1

(a) Testing
(b) Prevention
(c) Inspection
(d) Correction

1-b. GDP stands for (CO2, K1) 1

(a) Good Data Practice
(b) Good Documentation Practice
(c) Good Drug Practice
(d) Good Design Practice

1-c. Audit is a (CO3, K1) 1

(a) Routine task
(b) Systematic examination
(c) Inspection
(d) Punishment

1-d. Quality agreement is between (CO4, K1) 1

(a) QA & QC
(b) Contract giver & acceptor
(c) Regulator & firm
(d) Customer & seller

1-e. Control charts monitor (CO5, K1) 1

(a) Audit
(b) Profit
(c) Sales
(d) Variation

2. Attempt all parts:-

2.a.	Define Quality Control. (CO1, K1)	2
2.b.	What is Good Documentation Practice (GDP)? (CO2, K1)	2
2.c.	What is an internal audit? (CO3, K1)	2
2.d.	State the importance of quality agreements. (CO4, K1)	2
2.e.	What are statistical tools in quality control? (CO5, K1)	2

SECTION-B 20

3. Attempt all parts:-

3.a. Answer any one of the following:-

3.a.(i)	Explain the difference between Quality Control and Quality Assurance. (CO1, K2)	4
3.a.(ii)	Describe the evolution of quality concepts in pharmaceutical industries.(CO1, K2)	4

3.b. Answer any one of the following:-

3.b.(i)	Explain batch manufacturing and batch packaging records. (CO2, K2)	4
3.b.(ii)	Describe root cause analysis and its importance. (CO2, K2)	4

3.c. Answer any one of the following:-

3.c.(i)	Explain the steps involved in audit preparation. (CO3, K2)	4
3.c.(ii)	Explain the classification of audit observations. (CO3, K2)	4

3.d. Answer any one of the following:-

3.d.(i)	Explain the concept of quality agreements. (CO4, K2)	4
3.d.(ii)	Explain the role of ICH in pharmaceutical quality systems. (CO4, K2)	4

3.e. Answer any one of the following:-

3.e.(i)	Describe control charts and their applications. (CO5, K2)	4
3.e.(ii)	Explain histogram and its use in quality analysis. (CO5, K2)	4

SECTION-C 35

4. Answer any one of the following:-

4-a.	Explain Total Quality Management (TQM). Discuss its principles and applications in biotechnology industries. (CO1, K3)	7
4-b.	Describe the philosophy of Good Manufacturing Practices (GMP) and its importance in ensuring product quality. (CO1, K3)	7

5. Answer any one of the following:-

5-a.	Explain the significance of batch manufacturing and batch packaging records. (CO2, K3)	7
5-b.	Discuss the concept of retention samples and their role in quality assurance. (CO2, K3)	7

6. Answer any one of the following:-

6-a.	Discuss the preparation steps involved before conducting an audit. (CO3, K3)	7

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6-b.	Explain audit analysis and interpretation of audit findings. (CO3, K3)	7
7. Answer any one of the following:-		
7-a.	Discuss guidelines for managing contract manufacturing operations. (CO4, K3)	7
7-b.	Describe the principles of risk assessment and risk control. (CO4, K3)	7
8. Answer any one of the following:-		
8-a.	Describe control charts and their role in monitoring process variation. (CO5, K3)	7
8-b.	Explain tools of problem solving and continuous improvement. (CO5, K3)	7