

Time: (3 Hr)

Max. Marks:- 75

Q I Multiple choice questions

20 M

- 1 The Internal Audit activity has two clear functions of being an -
 - a Regulatory Control and Management Tool
 - b Internal Control and Management Tool
 - c Internal Control and Regulatory Control
 - d External Control and Management Tool

- 2 The basis for the impartiality of the audit and the objectivity of the audit conclusions is based on the principle of _____
 - a Confidentiality
 - b Independence
 - c Fair Presentation
 - d Integrity

- 3 Which of the following could be a possible source of a Critical Nonconformity?
 - a Preventive maintenance on a critical water system not conducted according to schedule
 - b Standard operating procedure review is overdue
 - c Open sterile products located in a non-aseptic area
 - d Cracks in Wall Surfaces

- 4 Which of the following could be a possible source of a Major Defect?
 - a Warehouse not cleaned according to the schedule
 - b Inadequate segregation of quarantine components
 - c Open sterile products located in non-aseptic area
 - d Standard operating procedure review is overdue

- 5 Trend analysis, internal audits, risk assessment are elements of _____ of the of quality system.
 - a Evaluation activities
 - b Manufacturing operation
 - c Resources
 - d Management responsibilities

- 6 Which of the following is one of the approach for conducting internal audit as per quality system regulation.
 - a Side-by-side approach
 - b Bottom-up approach
 - c Reverse approach
 - d Linear approach

- 7 Which of the following is false statement as per cGMP regulation for container and closures?
- a They are not required to be stored under quarantine after receipt until they have been tested or examined.
 - b Each drug product containers, or closures shall be identified with a distinctive code
 - c The containers of components selected shall be cleaned when necessary
 - d Sterile equipment and aseptic sampling techniques shall be used when necessary
- 8 One of the important components of risk assessment is _____
- a risk identification
 - b risk control
 - c risk review
 - d risk acceptance
- 9 New vendors must be qualified and approved before regular supply of raw materials by _____
- a QA department
 - b R & D department
 - c Purchase department
 - d Production department
- 10 A vendor shall be disqualified and removed from Approved vendors list for the following reason
- a If 3 out of 10 lots fail to comply the specification in a specified period under review.
 - b If 3 out of 20 lots fail to comply the specification in a specified period under review.
 - c If 1 out of 10 lots fail to comply the specification in a specified period under review.
 - d If 2 out of 10 lots fail to comply the specification in a specified period under review.
- 11 In the Packaging material Vendor audit, there has to be the sampling procedure for incoming materials refers to which part of Vendor Assessment Form
- a Personnel
 - b Premises
 - c Machines and Equipment
 - d Quality Systems
- 12 For any new Primary or Secondary Packaging material, QC personnel will send the specifications to the _____
- a Purchase Personnel
 - b QA Personnel
 - c Packaging Personnel
 - d Production Personnel

- 13 In auditing a microbiology laboratory, inspection of _____ should be given importance.
- a autoclave
 - b oven
 - c pH meter
 - d microscope
- 14 This test is performed to check that the medium is capable of allowing the microbes to thrive.
- a Growth promotion
 - b Negative control
 - c Sterility
 - d preservative efficacy
- 15 During auditing of microbiology laboratory, the inspection reveals that the stock culture is stored at 0°C. This deficiency will fall under the category-
- a Major
 - b other
 - c critical
 - d insufficient data
- 16 Microbiological reference standards include _____, endotoxin standards, biological indicators and microbial cultures
- a antibiotic standards
 - b water
 - c Packaging material
 - d Impurities
- 17 Control of air & water pollution is covered by _____ audit
- a ETP
 - b WFI
 - c Microbiology lab
 - d HVAC
- 18 The auditor of HVAC systems should be well versed with _____
- a engineering knowledge
 - b recruitment process
 - c pollution control regulations
 - d distillation technology
- 19 During auditing of water supply system, the inspection reveals that the installation manual is not available. This deficiency will fall under the category-
- a Other
 - b major
 - c critical
 - d insufficient data

- 20 Routine maintenance of water system will consist of _____
- a Replacement of heat exchangers
 - b cleaning of air filters
 - c addition of bleaching powder
 - d reversal of flow

Q II Answer the following (any two) 20 M

- 1 Give objectives of Auditing. Describe the methods of gathering audit information.
- 2 Explain the “Management Responsibilities and Resources” as an element of quality system
- 3 What is the importance of Effluent Treatment Plant? Highlight the major steps taken in the audit of ETP.

QIII Answer the following (any seven) 35 M

- 1 Enlist the types of Audits and explain each type briefly, Add a note on Management of audit
- 2 Define Nonconformity? Explain with suitable examples.
- 3 What is quality system approach? Explain in brief “manufacturing operations” element of quality system
- 4 What is quality risk management? Explain its various components.
- 5 Illustrate the importance of conducting vendor audits. Discuss packaging material vendor audit.
- 6 Describe the audit checklist of capsule production area.
- 7 Explain the significance of sterility testing, antibiotic assay and preservative efficacy test during auditing of the microbiology laboratory.
- 8 Explain in brief the points considered in auditing the HVAC system in relation with the environmental aspects of the plant.
- 9 Discuss the essential documents that are needed to be maintained for audit of microbiology laboratory.
