



TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF PURE AND APPLIED SCIENCES

UNIVERSITY EXAMINATION FOR:

BTAC/BTIC

ACH 4311: VALIDATION AND REGULATORY AFFAIRS PAPER 1

END OF SEMESTER EXAMINATION

SERIES: MAY 2016

TIME: TWO HOURS

DATE: MAY 2016

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of **FIVE** questions. Attempt **question ONE** and **any other TWO**.

Do not write on the question paper.

Question ONE

a) Write the following acronyms in full:

- | | | |
|-------|------|----------|
| (i) | GCPs | (1 mark) |
| (ii) | AQL | (1 mark) |
| (iii) | OOS | (1 mark) |

b) Define the following terms:

- | | | |
|-------|------------------------|-----------|
| (i) | Regulatory agency | (2 marks) |
| (ii) | Acceptance number (Ac) | (2 marks) |
| (iii) | Accuracy | (2 marks) |

c) State the following:

- | | | |
|------|---|-----------|
| (i) | The first THREE steps of problem solving process | (3 marks) |
| (ii) | The TWO management styles developed by Douglas McGregor | (2 marks) |

- (iii) THREE procedural policies of inspection and testing (3 marks)
- (iv) THREE advantages of motivation (3 marks)

d) Explain the following:

- (i) The term, “employee involvement” (3 marks)
- (ii) “Quality and accuracy” criterion for selecting testing laboratories (4 marks)
- (iii) The role of Kenya Bureau of Standards (KEBS) (3 marks)

Question TWO

- a) If 200 cans are examined and it is found that three (3) are low in proteins, two (2) are low in carbohydrates and proteins, and one (1) one low in fats, proteins and carbohydrates contents. Calculate the following:
 - (i) Nonconforming items (2 marks)
 - (ii) Total nonconformities (2 marks)
 - (iii) Percent nonconforming items (2 marks)
 - (iv) Number of nonconformities per 100 items (2 marks)
- b) Discuss the idea of Hawthorne illumination tests (12 marks)

Question THREE

- a) (i) Outline FIVE laboratory errors that may lead to out-of-specification (OOS) results (5 marks)
- (ii) Explain how properly trained and supervised laboratory personnel can help in preventing OOS results. (5 marks)
- b) Discuss, “Validation Report” as one of validation documentation (10 marks)

Question FOUR

- a) Outline one of the initial, threefold purpose (“Terms of Reference”) of the ICH (6 marks)
- b) Use the statement, “cornflakes are sold in 500g”, to illustrate the difference between sampling by attributes and variables (14 marks)

Question FIVE

- a) Describe the following:
 - i. the THREE stages of process validation (6 marks)
 - ii. the role of validation policy (8 marks)
- b) Outline the typical process of hiring new qualified people (6 marks)