



THE MOMBASA POLYTECHNIC UNIVERSITY COLLEGE

(A constituent of JKUAT)

Faculty of Applied and Health Sciences

DEPARTMENT OF PURE AND APPLIED SCIENCES

UNIVERSITY EXAMINATION FOR THE DEGREE OF BACHELOR OF
TECHNOLOGY IN APPLIED CHEMISTRY

ACH 4311 : VALIDATION AND REGULATORY AFFAIRS

SPECIAL/SUPPLEMENTARY EXAMINATION

FEBRUARY 2013 SERIES

2

HOURS

Instructions to candidates:

This paper consist of **FIVE** questions

Answer question **ONE** (compulsory) and any other **TWO** questions

Question ONE

- a) (i) State the TWO types of quality control (2marks)
- (ii) State the first two of the FIVE Maslow's hierarchy of needs (2marks)
- (iii) State the THREE most important regulations applying to validations (3marks)
- (iv) State the TWO management styles developed by Douglas McGregor. (2marks)
- b) (i) Define Taylorism (2marks)
- (ii) Define the term, 'consignment' (2marks)
- (iii) Define the term, 'Validation' according to the US food and drugs Administration's (FDA's), 1987 guideline. (2 ½ marks)
- c) (i) Outline TWO characteristics of a motivated person. (2marks)
- (ii) Outline the first two steps of problem solving process. (2marks)

- (iii) Outline one of the THREE purposes of international conference on Harmonization CICH). **(2marks)**
- d) (i) What is the role of Kenya Pharmacy and Poisons Board? **(3marks)**
- (ii) What is the role of Good Manufacturing Practices (GMPs) regulations? **(2marks)**
- (iii) What is the role of equipment logbook? **(3 ½ marks)**

Question TWO

- a) Define 'Sampling plan' according to IUPAC. **(2marks)**
- b) Explain the meaning of 'inspection and testing'. **(6marks)**
- c) Explain the objective of patrol inspection. **(6marks)**
- d) Differentiate between sampling by attributes and by variables using the following statement, "cornflakes are sold in packets of 500g" **(6marks)**

Question THREE

- a) Explain the term, 'method validation'. **(8marks)**
- b) Outline THREE reasons why an analytical method should be validated or revalidated. **(6marks)**
- c) State the first SIX steps of validation. **(6marks)**

Question FOUR

- a) State the FIVE types of documentation **(5marks)**
- b) Outline FIVE objectives of a quality manual **(10marks)**
- c) Outline FIVE common laboratory errors that may lead to out-of-specification situations. **(5marks)**

Question FIVE

- a) (i) Explain the meaning of term 'Linearity' **(6marks)**

(ii) Explain the use of signal-to-noise ratio (S/N)

(4marks)

b) Explain the consequences of setting Stringent limit values during a validation process.

(10marks)