



TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF PURE & APPLIED SCIENCES

UNIVERSITY EXAMINATION FOR:

MASTER OF SCIENCE IN CHEMISTRY

ACH 5114: ADVANCED QUALITY ASSURANCE TECHNIQUES

SPECIAL/ SUPPLIMENTARY EXAMINATIONS

SERIES: SEPTEMBER 2018

TIME: 3HOURS

DATE: Pick Date Sep 2018

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of **SIX** Question(s). Attempt any **FOUR** questions.

Do not write on the question paper.

Question ONE

- a) Define cGMP and state its importance (5 marks)
- b) Discuss at least five (5) requirements of a cGMP (10 marks)
- c). List the details to be included in a processing instructions (10 marks)

Question TWO

- a). Discuss the pertinent consideration prior to purchase, construction, or alteration of existing facilities (10 marks)
- b) Discuss the measures to be avoided for cross-contamination by appropriate technical personnel (10 marks)
- c) Discuss the benefits of conducting environmental auditing (5 marks)

Question THREE

- a) Differentiate between batch processing and batch packaging processing records (10 marks)
- b). Discuss the importance of equipment labelling and calibrating (10 marks)
- c) List other systems, parameters and/or facilities which are required in the factory building (5 marks)

Question FOUR

- a) Describe any five (5) things which should be include in a receipt (5 marks)
- b) List the specification required to be provided for pharmaceutical products (5 marks)
- c) Explain the different Personal hygiene components which needs to be undertaken for cGMP (10 marks)
- d) Discuss the consequences of non-implementation of cGMP (5 marks)

Question FIVE

- a) Differentiate between tactical and strategic outsourcing (5 marks)
- b) List ten (10) types of required GMP documents (10 marks)
- c) Explain the reason for the Recall of a product (10 marks)

Question SIX

- a) c) Discuss the 5–S practice used to establish and maintain quality environment in an organization (5 marks)
- b) Differentiate between the contract giver and contract acceptor (10 marks)
- c) Explain why documentation is necessary for quality assurance system (10 marks)