



National Quality Control Laboratory

P.O. Box 29726, KNH Nairobi • Telephone: 2726963 • Fax: 2718073

GUIDELINES FOR SUBMITTING SAMPLES TO THE NATIONAL QUALITY CONTROL LABORATORY

REVIEW DATE: 18TH OCTOBER 2007
SUPERCEDES: NONE

“Quality Medicines Protect”

TABLE OF CONTENTS

1.0	Title Page
2.0	Table of Contents
3.0	Preface
4.0	Categories of clients
5.0	Guidelines
6.0	Laboratory analysis
7.0	Payment
8.0	Analysis report
9.0	Appeals
10.0	Transportation of Samples to the Laboratory

1.0 Preface

These guidelines are intended to assist applicants in submitting samples to the National Quality Control Laboratory for evaluation.

The integrity of samples and the validity of analytical results require that certain conditions exist upon receipt of samples by the laboratory.

All clients are required to fill a sample analysis request form which is available at the Laboratory sample receiving office of the laboratory's web site.

2.0 Guidelines

The following requirements must be met when submitting samples at the Laboratory.

2.1 Sample packaging requirements

Samples must be submitted in the appropriate properly sealed and labeled containers.

2.2 Sample identification requirements

Samples submitted for analysis shall be accompanied by a test request form dully filled by the client and shall contain the following information:

- a. Client name and Address
- b. Product name
- c. Product label claim
- d. Lot number/Batch number
- e. Sample size (Quantity in a package/pack size)
- f. Date of manufacture
- g. Date of Expiry
- h. Storage conditions
- i. Tests requested
- j. Name, Signature, Designation and Date of responsible person for the request.

2.3 Sample size requirements

The size of sample is dependent on;

- The and types and number of tests requested,
- The reason for the request which could vary from reasons such as batch release, registration, post marketing surveillance, tenders or counterfeits.

The minimum number of samples to be submitted is indicated in the table below.

FORMULATION	PACK SIZE	MINIMUM NO. OF SAMPLES REQUIRED
Tablets/ capsules	All	100 Tablets/Capsules
Suspension/Syrups	≤ 50mL	20 Bottles
	10 - 100mL	
	> 10mL	
	≥100mL	
Injectables	≤10mL	100 Vials/ Ampoules
	10 - 100mL	50Vials/ Ampoules/Bottles
	≥100mL	10 Bottles
Creams/Ointments	≤ 5g	50 Tubes
	5 - 50g	20Tubes/Jar
	≥ 50g	5Tubes/Jars
Eye/Ear Drops	< 10mL	100 Bottles
	≥	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g

2.4 Registration Samples from Regulatory bodies

All samples should have at least two-thirds of their shelf life remaining at the time of receipt.

2.5 Non - pharmacopoeial samples

These samples must be accompanied by:

- The manufacturer's methods of analysis including finished product specifications and validation data;
- Chemical reference Substances together with their certificates of analysis.

2.6 Drug Donation samples

Pharmaceutical products donated through goodwill or Disaster management should be submitted to the laboratory accompanied with relevant documentation from the Office of the President Special Programmes as well as the Pharmacy and Poisons board.

3.0 Laboratory Analysis

3.1 Time frame for analysis

The usual duration for completing evaluation on a sample is 2 - 3 weeks. However this duration may vary from one sample to another. No client is allowed to communicate directly with the analyst.

4.0 Payments

Private clients are issued with a proforma invoice and are required to pay 50% of the total cost of analysis during sample submission. The remaining 50% will be paid upon issuance of an invoice and final analysis report.

Upon request, a detailed report is issued to the client with an added fee of 20% of the total cost of analysis.

Only one certificate of analysis (COA) is issued per sample and certified copies are provided at an additional cost of Kshs 1000 per copy.

All Payments shall be made in banker's cheque or company cheques and are made payable to the **NATIONAL QUALITY CONTROL LABORATORY**.

5.0 Analysis Report

Analytical results are reported in form of an official certificate which must bear Director's signature and the laboratory's notary seal.

Where different batches are submitted, each batch is treated as an independent sample and hence each is issued with its own certificate of analysis.

6.0 Appeals

Clients that are dissatisfied with the analysis report issued should contact the Laboratory's management for guidance on the appropriate procedure for handling complaints.

Disclaimer:

Transportation of samples to the National Quality Control Laboratory;

It is the responsibility of the client to ensure safe transport of samples to the Laboratory unless under specific cases where the Laboratory assumes the responsibility of transporting the samples for analysis. In the latter, the Client shall make the request in writing and bears the cost of such an excise.

Samples that require thermal preservation must be transported on ice and still cooling by the time of receipt.

The institution reserves the right to accept or reject samples if any of these conditions are not met.