National Quality Control Laboratory
Hospital Road , KNH Complex, P.O. Box 29726, 00202 Nairobi, Kenya
Telephone: 2726963, +254 - 020 - 3544525/30 • Fax: 2718073
Email: info@nqcl.go.ke Website: www.nqcl.go.ke

GUIDELINES FOR SUBMITTING SAMPLES TO THE NATIONAL QUALITY CONTROL LABORATORY

REVIEW DATE: 11th March 2013
SUPERCEDES: Version 01

"Quality medicines Protect"

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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.

Sample Submission Guidelines

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

Sample packaging requirements

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

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.

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	≤ 50 mL	20 Bottles
	10 – 100 mL	
	> 10 mL	
	≥100 mL	
Injectables	≤10 mL	100 Vials/Ampoules
	10 - 100 mL	50 Vials/Ampoules/Bottles
	≥100 mL	10 Bottles
Creams/Ointments	≤ 5 g	50 Tubes
	5 - 50 g	20 Tubes/Jars
	≥ 50 g	5 Tubes/Jars
Eye/Ear Drops	< 10 mL	100 Bottles
	≥ 10 mL	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5 g

Registration Samples from Regulatory bodies

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

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 (200 mg minimum to 1gram maximum) together with their certificates of analysis.

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 Programs as well as the Pharmacy and Poisons board.

Laboratory Analysis

Time frame for analysis

The usual duration for completing evaluation on a sample is 42 working days. However this duration may vary from one sample to another.

Note: No client is allowed to communicate directly with the analyst.

Payments

Private clients are issued with a proforma invoice and are required to pay at least 80% of the total cost of analysis during sample submission. The remaining 20% will be paid upon issuance of an invoice and final analysis report.

Note: Clients submitting tender samples for analysis are required to pay the total cost of analysis during sample submission.

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**.

Analysis Report

Analytical results are reported in form of an official certificate which must bear the 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.

Complaints

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

Appeals

Clients who are dissatisfied with the issued laboratory results and would want to request for re-analysis of the samples, are required to;

- Submit three different batches of the same formulation and strength
- Pay double the original cost of analysis per batch
- Pay the total cost of analysis at the time of sample submission.

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.