Republic of Kenya

Ministry of Health

National Quality Control Laboratory

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GUIDELINES FOR SUBMITTING SAMPLES TO THE NATIONAL QUALITY CONTROL LABORATORY

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Preface

These guidelines are intended to inform clients on the requirements to be met when submitting samples to the National Quality Control Laboratory for testing.

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

1.0 Sample Submission Guidelines

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

1.1 Sample Packaging

Samples must be submitted in their original, untampered packaging, in properly sealed and labelled containers**.**

Samples that require storage at temperatures below ambient must be delivered in appropriate temperature-controlled containers that ensure maintenance of cold chain, accompanied by documentation demonstrating that the required temperature conditions were maintained throughout transportation.

1.2 Official Analysis Request

Samples submitted for analysis must be accompanied by an **Analysis Request Form** duly filled by the client in **DUPLICATE**. The forms are available at the Laboratory's sample receiving office and can be downloaded from the Laboratory's website (https://nqcl.go.ke).

The forms shall contain the following information:

a. Name and address of applicant (company);

b. Company telephone number and email address;

c. Name and presentation of product;

d. Name and address of manufacturer;

e. Reason for Test (pre-registration/post-marketing surveillance/pre-distribution/investigative/research/other – specify)

f. Sample information which shall include:

   i. Batch/Lot number;

   ii. Date of product manufacture;

   iii. Date of expiry;

   iv. Name(s) and amount of active ingredients on product label;

g. Sample size (Quantity in a package/pack size);

h. Applicant's reference number;

i. Storage conditions;

j. Tests requested;

k. Method of analysis/monograph;

l. List of other items submitted alongside the sample e.g. working reference standard;

m. Name, Date, Signature and Designation of person authorizing request for analysis;

n. Telephone number and email address of person authorizing request for analysis.

1.3 Sample Size

The size of sample is dependent on:

- Types and number of tests requested;
- The reason for the request which could be batch release, registration, post market surveillance, tenders, counterfeits among others.

The minimum number of samples to be submitted is summarized in the table below:

FORMULATION	PACK SIZE	MINIMUM NO. OF SAMPLES REQUIRED
Tablets and capsules	All	120 Tablets/Capsules
Suspensions and Syrups	< 10 mL	50 Bottles
	10 – 900 mL	20 Bottles
	1000 – 2000 mL	10 Bottles
	> 2000 mL	4 Bottles
Injectables	< 10 mL	100 Vials/Ampoules/pre-filled syringes
	10 – 100 mL	50 Vials/Ampoules/Bottles
	110 – 2000 mL	10 Bottles
	> 2000 mL	6 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	20 Packs
Active Pharmaceutical Ingredients	All	5 g
Powders for Oral Preparations	5 – 100 g	100 sachets
	> 100 g	50 sachets
Transdermal Patches	5 – 100 g	100 sachets
	> 100 g	50 sachets
Male Condoms	All	800 Pieces*
Gloves	All	300 – 600 Pieces*

* - *Actual sample size shall be determined by the batch size of interest; these shall be discussed at the time of quotation preparation.*

1.4 Registration Samples from/by Regulatory Bodies

All samples should have at least one year of their shelf-life remaining at the time of receipt. Exception shall be given on special samples like, post market surveillance, pharmacovigilance and research samples.

1.5 Non - Pharmacopoeia Samples

These samples must be accompanied by the manufacturer's methods of analysis including finished product specifications and analytical method validation data.

1.6 Drug Donation Samples

Pharmaceutical products donated through goodwill or disaster management should be submitted to the Laboratory accompanied by relevant documentation from the Office of the President Special Programs or the relevant government Department as well as the Pharmacy and Poisons board.

1.7 Chemical Reference Standards

All submitted samples must be accompanied by chemical reference standards or working standards (200 mg – 1.0 g), together with their valid certificates of analysis. The standards must have at least 6 months of their shelf-life remaining at the time of submission.

The certificate of analysis must indicate the source, batch number, potency, storage conditions and expiry/retest dates. For working standards, the certificate must contain traceability details (The batch number of the primary/reference standard indicated on the working standard COA).

The working/reference standards must be packed in clearly labelled amber-colored vials and must be transported and stored under specified controlled conditions of temperature and humidity.

2.0 Laboratory Analysis

2.1 Time Frame for Analysis

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

2.2 Expired Samples

Where a sample expires before the commencement or conclusion of analysis, the Laboratory shall inform the client and request for a fresh sample as appropriate, and state the intent to dispose of the expired sample in line with Laboratory procedures. If there shall be no response from the client within six (6) months, the samples shall be disposed off according to the sample disposal procedures as outlined in NQCL/SOP/ADDO-006.

2.3 Payments

All clients shall be issued with a quotation prior to sample submission and are required to make full payment during or before sample submission. All Payments shall be made exclusively through the **official eCitizen payment platform**. Payments made through any other channel shall not be accepted.

Clients shall follow the steps outlined below to complete payment through the eCitizen USSD process:

1. Dial ***222#** on your mobile phone.
2. Select 1 – Make payment.
3. Select 2 – Enter Service Code and enter **NQCLTS.**
4. Enter the reference number (Name of Organization or Company).
5. Enter the amount to pay.
6. Enter your M-PESA PIN.
7. Press OK to complete the payment.

NB: If you wish to use other payment methods other than MPESA, cancel the STK push on your mobile phone and click the link sent via SMS to select your preferred payment

method.

Clients who require a payment refund shall contact the Laboratory's Accounts office for guidance.

2.4 Analysis Report (COA)

Analysis results are reported in form of an official Certificate of Analysis (COA) which must bear the Director's signature and the Laboratory's notary seal/official stamp. Where different batches are submitted, each batch is treated as an independent sample and hence each is issued with its own COA.

Only one COA is issued per sample and certified copies are provided at an additional cost of Ksh. 1,000.00 per copy upon written request by the client. The request should be addressed to the Director, NQCL and should cite reasons for the COA copy.

Upon request, a detailed report shall be issued to the client at an additional fee.

A copy of COA for each sample analyzed shall be submitted to the Drug Regulatory Authority, the Pharmacy and Poisons Board.

3.0 Confidentiality

No client is allowed to communicate directly with any analyst.

4.0 Complaints

Clients who are dissatisfied with the analysis progress or reports issued should contact the Sample Management Unit of the Laboratory for guidance on the appropriate procedure for reporting and handling complaints.

5.0 Appeals

Clients who are dissatisfied with the issued laboratory results and would want to request for re-analysis of the samples are required to present their request in writing to the

Director, NQCL, from where further guidance shall be given.

The requests for appeal must be made within 30 days after collection of the Certificate of Analysis after which the window for complaints shall be closed. All appeals shall be handled as outlined in NQCL/SOP/ADDO-019.

6.0 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.