	Title: Guideline for receipt of samples in the laboratory	
Rev No: 01	**Doc No: PBSL/GL/020**	Version #: 02
Issue date: 15 may 2024	**Effective date: 17 Feb 2024**	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone
PMB 322
Central Medical Stores Compound
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ACKNOWLEDGEMENTS

EXECUTIVE SUMMARY

1.0 INTRODUCTION

These guidelines are intended to assist applicants in submitting samples to the National Pharmaceutical Quality Control Laboratory (NPQCL), Pharmacy Board of Sierra Leone (PBSL) for evaluation.

2.0 OBJECTIVE

To check the integrity of samples and the validity of analytical results that are required to ensure certain conditions exist upon receipt of samples by the laboratory.

3.0 SCOPE

All samples received by the lab for laboratory analysis

4.0 SPECIFIC REQUIREMENTS

4.1 Category of Client

The departments of the Pharmacy Board of Sierra Leone is the major client of the National Pharmaceutical Quality Control Laboratory.
All clients are required to fill a sample analysis request form which is available at Registration or Drug Information & Pharmacovigilance or Inspection Departments of the Pharmacy Board of Sierra Leone.

4.2 Guidelines

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

4.2.1 Sample packaging requirements

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

4.2.2 Sample identification requirements

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

a. Sample code
b. Product name
c. Product label claim
d. Product Lot number/Batch number
e. Sample size (Quantity in a package/pack size)
f. Date of manufacture
g. Date of Expiry
h. Manufacturer's name and address
i. Storage conditions
j. Tests requested
k. Laboratory number
l. Name, Signature, Designation of responsible person for the request and date

4.3 Sample size requirements

The size of sample is dependent on;

- The type 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 to the NPQCL for new registration is indicated in the table below:

FORMULATION	**PACK SIZE**	**MINIMUM NO. OF SAMPLES REQUIRED**
Tablets/capsules	All	120 Tablets/Capsules
Suspension/Syrups	≤ 50mL	50 Bottles
	50mL	50 Bottles
	100mL	50 Bottles
Injectables	≤ 10mL	100 Vials/Ampoules
	10 – 100mL	50 Vials/Ampoules/Bottles
	≥ 100mL	50 Bottles
Creams/Ointments/Lotions	≤ 5g	50 Tubes
	5 – 50g	50 Tubes/Jars
	≥ 50g	50 Tubes/Jars
	< 10mL	50 Bottles
	10 – 100mL	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g
ORS	All	50 Packs

For submission of Samples for Post Market Surveillance, the minimum number of samples to be submitted are:

FORMULATION	**PACK SIZE**	**MINIMUM NO. OF SAMPLES REQUIRED**

Tablets/capsules	All	120 Tablets/Capsules
Suspension/Syrups	≤ 50mL	20 Bottles
	50mL	6 Bottles
	100mL	6 Bottles
Injectables	≤ 10mL	100 Vials/Ampoules
	10 – 100mL	50 Vials/Ampoules/Bottles
	≥ 100mL	10 Bottles
Creams/Ointments/Lotions	≤ 5g	50 Tubes
	5 – 50g	20Tubes/Jars
	≥ 50g	5 Tubes/Jars
	< 10mL	100 Bottles
	10 – 100mL	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g
ORS	All	30 Packs

4.4 Registration Samples

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

4.5 Non – pharmacopoeial samples

These samples must be accompanied with:

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

4.6 Drug Donation samples

Pharmaceutical products donated through good will or Disaster management should be submitted to the laboratory accompanied

with relevant documentation from the Director of Drugs and Medical Supplies and Pharmacy Board of Sierra Leone.

4.7 Laboratory Analysis

4.7.1 Time frame for analysis

The usual duration for completing evaluation on a sample is 2 – 4 weeks.

However this duration may vary from one sample to another.

No client is allowed to communicate directly with analysts.

4.7.2 Payments

All payments by private clients must be made through the office of the Registrar, Pharmacy Board of Sierra Leone.

Upon request, 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.

All Payments shall be made in cash or banker's cheques or company cheques and are made payable to the **Pharmacy Board of Sierra Leone**.

4.7.3 Analysis Report

Analytical results are reported in the form of an official certificate which must bear manager, supervisor and the analyst signature with the laboratory stamp.

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

certificate of analysis. In the case of post market surveillance, the same batch collected from different areas will be analysed as different samples

4.8 Appeals

Clients that are dissatisfied with the analytical report issued should contact the office of the Registrar for guidance on the appropriate procedure for handling complaints.

Disclaimer: Transportation of samples to the National Pharmaceutical Quality Control Laboratory;

It is the responsibility of the client to ensure safe transport of samples to the Laboratory,
unless under specific cases 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 exercise.

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

The institution reserves the right to accept or reject samples if any of the above condition(s) are not met.

5.0 GLOSSORY

NONE

6.0 REFERENCES

NONE

7.0 ANNEXES

NONE

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