MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REPORT FOR RISK BASED POST MARKETING SURVEILLANCE OF SELECTED ANALGESICS, ANTIBIOTICS AND CONTRACEPTIVES IN THE KENYAN MARKET

December 2025

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For clarifications, comments, or suggestions, please contact:

The Chief Executive Officer

Pharmacy and Poisons Board

P.O. Box 27663 – 00506, Nairobi

Telephone: 0709770100

Email: info@pharmacyboardkenya.org

Website: www.pharmacyboardkenya.org

EXECUTIVE SUMMARY

The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority of Kenya, established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. Under Section 3(b) of the Act, the Board is mandated to conduct post-market surveillance to ensure the safety and quality of health products and technologies (HPTs). In fulfillment of this mandate, the Pharmacy and Poisons Board implemented a routine, proactive post-marketing surveillance programme for selected HPTs.

A risk-based approach was applied in the selection of high-priority brands and batches. Samples were collected from Pharmaceutical Wholesalers, Retail pharmacies, and Healthcare facilities at National, County, and Sub-County levels across the country as determined by the distribution records provided by the Marketing Authorization Holders (MAH)/Local Technical Representatives (LTR) and distributors.

A total of 140 samples were collected and subjected to visual and physical inspection, as well as a review of product information. Of these, 110 samples underwent Minilab screening tests, while 46 samples were subjected to confirmatory testing using compendial analytical methods. Overall, 109 samples complied with Minilab, and 42 samples met compendial specifications for the test parameters analyzed. All non-compliant products (one from minilab screening and four from compendial analysis) were subjected to regulatory actions.

Monitoring of the quality of HPTs in the Kenyan market is essential for ensuring their safety and efficacy, ultimately leading to better patient outcomes and enhancing public confidence in the healthcare system.

Dr. Ahmed I. Mohamed
Ag. Chief Executive Officer

ACRONYMS & ABBREVIATIONS

AMR	Antimicrobial Resistance
EAC	East African Community
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
HPTs	Health Products and Technologies
LMICs	Low- and Middle-Income Countries
LTR	Local Technical Representative
MAH	Marketing Authorization Holder
MEDS	Mission for Essential Drugs and Supplies
OOS	Out of Specification
PPB	Pharmacy and Poisons Board
RB-PMS	Risk Based Post Marketing Surveillance
PMS	Post Marketing Surveillance
SF	Substandard and falsified
WHO	World Health Organization

DEFINITION OF TERMS

Falsified Health products or health technology	A product that is deliberately and fraudulently mislabeled with respect to identity and / or source.
Post marketing surveillance	All the processes that are carried out to continuously track/ monitor quality, safety and efficacy of medicines in the market (after registration).
Proactive Post marketing surveillance	Coordinated surveys, sampling and analysis, evaluation and assessment of regulatory requirements in relation to labelling, storage etc.
Reactive Post marketing surveillance	Follow up on complaints from spontaneous reporting.
Substandard Health product or health technology	Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.

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The Pharmacy and Poisons Board would like to extend its appreciation to the team who played a vital role in the development of the protocol and report on Post Marketing Surveillance (PMS) for selected health products and technologies in Kenya. The Board also extends its appreciation to the dedicated sample and data collectors whose efforts were key to the success of this survey, County Governments, and the Mission for Essential Drugs and Supplies, as well as to the outlets that supported sample collection.

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ABSTRACT

Background: Health products and technologies (HPTs) are critical components in the healthcare delivery system and are important in disease diagnosis, prevention, and case management. The World Health Organization (WHO) estimates that 10% of HPTs circulating in low- and middle-income countries (LMICs) are either substandard or falsified (SF). Substandard and Falsified (SF) HPTs can cause treatment failure and adverse reactions, increase morbidity and mortality, and contribute to the development of drug resistance. Vulnerable populations and patients with comorbidities are at particular risk of being harmed from receiving SF HPTs.

Objective: To conduct a Risk-Based Post Marketing Surveillance (RB-PMS) quality survey of selected health products in the Kenyan market.

Methods: This survey utilized a descriptive cross-sectional study design with quantitative methods for data collection, which took place in June 2025. A risk-based approach was used to prioritize products previously reported to the PPB for suspected non-compliance with approved specifications or marketing authorizations requirements, those with a recall history within the past three years, and products from new or high-risk manufacturers, particularly those with a record of significant GMP deficiencies or non-compliances. The risk-based approach targeted antibiotics, analgesics, and female hormonal contraceptives due to their high prevalence of use within the Kenyan population and their public health significance.

Samples were collected across the various levels of the supply chain based on the distribution list provided by the MAH/LTR and distributors. Samples were then subjected to Physical/ visual Inspection, Minilab™ screening, and Compendial testing at the Pharmacy and Poisons Board (PPB) Quality Control Laboratory, and the Mission for Essential Drugs Supplies (MEDS) laboratory.

Results: A total of 140 samples were collected from 60 facilities: public (55), private (5); distributed in 22 counties. Twenty-two (22) facilities monitored both temperature and humidity, 7 monitored temperatures alone, while 31 did not monitor temperature or humidity. A total of 110 samples underwent Minilab screening tests, while 46 samples were subjected to confirmatory testing using compendial analytical methods. Overall, 109 samples complied with Minilab, and 42 samples met compendial specifications for the test parameters analyzed.

Conclusion: This risk-based PMS identified five (5) non-compliant products, highlighting regulatory and supply chain vulnerabilities. All non-compliant products were subjected to regulatory actions. It is recommended that HPT storage facilities must monitor and record temperature and humidity as per the manufacturer's specifications. Compliance should be enforced through routine GDP inspections and County supervisory activities. Future surveillance should prioritize previously unassessed regions and HPT brands.

1. INTRODUCTION

1.1. Background

Health products and technologies (HPTs) are critical components in the healthcare delivery system and are important in disease diagnosis, prevention and case management. The World Health Organization (WHO) estimates that 10% of HPTs circulating in low- and middle-income countries (LMICs) are either substandard or falsified (SF)[1]. Substandard and Falsified (SF) HPTs can cause treatment failure and adverse reactions, increase morbidity and mortality, and contribute to the development of drug resistance. Vulnerable populations and patients with comorbidities are at particular risk of being harmed from receiving SF HPTs. Poor-quality HPTs also increase healthcare costs to both patients and the health system, wasting resources that could otherwise be used to benefit public health.

The increase in the number of poor-quality medicines in national and global markets presents an acute and often devastating public health crisis[2]. These critical medications, when compromised in quality, pose unique and severe risks that extend beyond general treatment failure, impacting individual patient outcomes, public health, and the broader healthcare system[3]. Substandard antibiotics directly fuel the global crisis of antimicrobial resistance (AMR), leading to untreatable infections, increased morbidity and mortality, and escalating healthcare costs[4].

Regionally, the East African Community (EAC) has reported recurring challenges in the quality of pharmaceuticals, particularly antibiotics and analgesics, which are among the most consumed medicines[5].

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[1] (Porter, M. E., & Teisberg, E. O., 2006)

[2] World Health Organization Substandard and falsified medical productsSkip to main content WHO / Sergey Volkov Multicoloured pills and tablets mixed together © Credits SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS 3 December 2024 KEY FACTS * Substandard and falsified.

[3] World Health Organization (WHO). (2017). *A study on the public health and socio-economic impact of substandard and falsified medical products*. World Health Organization.

[4] Newton, P. N., Fernandez, F. M., Plançon, A., Baudouin, B., Fauré, K., Guerin, B., ... & Green, M. D. (2016). A review of medical products identified as falsified or substandard over the last 10 years. *Malaria Journal*, *15*(1), 83.

[5] EAC-MRH, 2018

Report on the assessment of locally manufacturing capacity for Medicine in Kenya indicated that anti-infectives had the largest number of product formulations (55 out of 215) being locally manufactured, followed by cardiovascular formulations (28 out of 98), and thirdly medicines for pain and palliative care (27 out of 50)[6].

Data has consistently indicated a significant prevalence of poor-quality medicines in the East African market, with estimates suggesting that as high as 18.7% of medicines in Africa, including East Africa, are substandard or falsified, and specific studies in countries like Kenya demonstrating high failure rates for common antibiotics, such as 37.7% for Amoxicillin formulations in Nairobi[7].

The Pharmacy and Poisons Board (PPB) has recently conducted post-market surveillance (PMS) on antimalarials and products utilized in Public Health and Maternal, Newborn, and Child Health (MNCH) from 2022 to May 2025. This assessment yielded a highly positive average pass rate of 99.25%. Despite these favorable findings, the PPB continues to receive market complaints regarding the quality of antibiotics, analgesics, and emergency contraceptives. Most of these complaints have necessitated regulatory actions, including recalls and quarantines of confirmed poor-quality products. Notably, internal PPB analysis indicates that the highest volume of these complaints originated from local manufacturers in Kenya.

1.2. Problem Statement and Justification

The presence of substandard, falsified, or degraded medicines in the Kenyan market poses a serious threat to public health and undermines trust in the healthcare system. The National Regulatory Authority has received multiple complaints regarding the quality and therapeutic effectiveness of commonly used Analgesics, Antibiotics, and Emergency Contraceptives. These complaint products are manufactured both locally and in countries such as China, India, and Bangladesh—regions with varying levels of GMP compliance among pharmaceutical manufacturers. In the last three years, 44.4% the complaints came from Kenya, 35.8% from India, 4.31% from China and 3.9% from Bangladesh

Despite existing regulatory frameworks, there remains a gap in routine, evidence-based verification of whether medicines circulating in the market consistently meet market authorization conditions and quality standards. There

[6] MOH Kenya, 2024. The Report on The Assessment of Local Manufacturing Capacity for Medicines in Kenya.
[7] Ozawa, S., et al. (2018). Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. *PLoS Medicine*.

is limited data that connects product quality to manufacturing origin, GMP status, and the types of complaints received.

This Post-Market Surveillance (PMS) study is therefore critical to verifying the quality and regulatory compliance of selected medicines in these three therapeutic classes. By assessing their conformance to market authorization requirements, detecting substandard or falsified products, and generating actionable data, the study will support evidence-based regulatory inspections, enforcement actions, and inform risk-based planning for future surveillance activities.

2. OBJECTIVES

2.1. General objective

Conduct a Risk-Based Post Marketing Surveillance (RB-PMS) quality survey of selected health products in the Kenyan market.

2.2. Specific objectives

a. To verify the quality and regulatory compliance of selected analgesics, antibiotics, and emergency contraceptives circulating in the Kenyan market by assessing their conformance to market authorization requirements.
b. To detect substandard and falsified products and support evidence-based regulatory action to safeguard public health.
c. To generate data that informs risk-based decision-making, including regulatory inspections, enforcement, and future surveillance planning.

3. METHODOLOGY

3.1. Surveillance Scope and Duration

The risk-based post-market quality survey prioritized products previously reported to the PPB for suspected non-compliance with approved specifications or marketing authorization requirements, those with a recall history within the past three years, and products from high-risk manufacturers, particularly those with a record of significant GMP deficiencies or non-compliances.

Where feasible, sampling targeted complaint batches, related campaign batches, and other relevant product brand batches. Under risk-based considerations, priority was given to high-risk regions, areas where the implicated batches were distributed, and facilities where quality-related complaints originated, as identified through available distribution data.

A centrally coordinated sampling strategy was implemented to ensure national coverage and consistency across teams. By the end of the exercise, each sampling team was expected to contribute a total of four batch samples per product brand.

Product sampling was conducted between 25th and 30th June and included the collection of samples from:

- Distributors and wholesalers,
- Retail pharmacies, and
- Public and private healthcare facilities.

The schedule for technical activities was as follows:

- Sample and data collection: 6 days
- MiniLab screening: 7 days
- Compendial laboratory testing: 42 working days

3.2. Selection of Product

The antibiotics, analgesics, and female hormonal contraceptives targeted for the 2024/2025 Post-Market Surveillance (PMS) exercise were selected based on the product categories prioritized in the Three-Year Strategy for Post-Marketing Surveillance of Health Products and Technologies in Kenya. These categories were chosen due to their high prevalence of use within the Kenyan population and their public health significance.

In compiling the final list, special consideration was given to products sourced from high-risk regions, including the local market, India, Bangladesh, and China, based on global regulatory intelligence and historical compliance trends.

A risk-based approach was applied to identify high-priority brands and batches using data from multiple PPB regulatory databases over the past three years—including Quality Control/Post-Market Surveillance (QC/PMS), Marketing Authorization (MA) and GMP/GDP inspections. This analysis informed the compilation of the following product-specific risk lists:

- Non-Complying Products List: Products previously associated with laboratory test failures or other forms of non-compliance.
- Manufacturer Risk History List: Products from manufacturers classified as high-risk or those with a history of GMP non-compliance.
- Product Quality Complaints List: Products frequently linked to field complaints, adverse quality findings, or recalls.
- Non-Routine Marketing Authorization List: Products granted MA through non-standard procedures, including donations or compassionate-use batches.

Lists of selected product brands within the analgesic, antibiotic, and contraceptive categories were compiled. Each product was identified by its brand name and manufacturer to ensure traceability and facilitate targeted sampling.

3.3. Selection of product Batches

To ensure efficient use of available resources while maintaining adequate representation, a total of four batches per selected product brand from each specific manufacturer were targeted for sampling.

The selection of batches was guided by the following risk-based considerations:

- Complaint Batches: Batches linked to previously reported product quality complaints were prioritized and included where applicable.
- Campaign Batches: Batches distributed under specific national supply campaigns were prioritized over non-campaign batches due to their wide-scale distribution and public health impact.
- One Batch per Facility: Sampling was limited to one batch per facility to ensure broad geographic representation and avoid duplication.
- Linked Quality Concerns: Where unrelated batches of the same product or from the same manufacturer had a history of poor quality, these were considered in the selection to strengthen surveillance focus.

3.4. Selection of Sampling Regions

Sampling regions were identified based on distribution data provided by MAH/LTRs and distributors, ensuring traceability of selected product batches across the supply chain.

In addition, certain high-risk regions within Kenya were prioritized using the following criteria:

- Climatic stress factors: Areas with high relative humidity and elevated temperatures, which can accelerate product degradation and compromise stability.
- Border counties: Regions adjacent to international borders were included due to their increased vulnerability to unauthorized cross-border trade and circulation of substandard or falsified products.
- Historical risk data: Regions previously associated with frequent product quality complaints or recalls were also prioritized.

This selection approach was designed to enhance the likelihood of detecting substandard or degraded products and to ensure geographically diverse coverage aligned with the risk-based surveillance strategy. The selected regions included the coastal region, the Lake Victoria region, North rift, Nairobi and its environs, and northern Kenya.

3.5. Determination of the Final List of Products and Batches

The final list of products selected for the 2024/2025 PMS exercise—including product name, brand name, and batch number—was developed using a risk-based approach that integrated multiple data sources and prioritization criteria

Table 1 List of medicines selected for sampling and testing

S. No.	Product Category	Active Ingredient	Product Brand	Quantities per sample	Batch Number	Manufacturer	Country of Origin
1.	Antibiotics	Amoxicillin	Alimox	20 bottles	01659AMS and 3 other batches in the market	Sphinx Pharmaceuticals Ltd	Kenya
			Moximed Capsules	100 capsules	P3317 and 3 other batches in the market	Medivet Products Ltd	Kenya
			Kemoxyl DT	100 tablets	86253, 83230, 83231 and any other batch in the market	Laboratory & Allied Ltd	Kenya
		Amoxicillin & Clavulanic Acid	Rapiclav 312.5 DT	100 tablets	Any 4 batches in the market	IPCA Laboratories Ltd	India
		Ampicillin/ Cloxacillin	Cloxam	20 bottles	0087CXS, 0089CXS and 2 other batches	Sphinx Pharmaceuticals Ltd	Kenya
		Azithromycin	C-Azi	90 tablets	G307E2011 and 3 other batches in the market	Innova Captab Limited	India
			Izzithree	20 bottles	Any 4 batches in the market excluding 149A, BPL 068A, 227A	Biopharma Ltd	Kenya
			Shalzin	90 tablets	BN 3373450 and 3 other batches in the market	Shalina Laboratories Pvt Ltd	India
			Zimycin	90 tablets	BN ZIU022301 and 3 other batches in the market	Saga Lifesciences Ltd	India
			Azithrosafe Suspension	20 bottles	Any 4 batches in the market excluding BN GE04139	Enicar Pharmaceuticals Pvt Ltd	India
		Benzathine Penicillin	Benzapene 2.4 MU	50 vials	BN 202103131 and 3 other batches in the market	Reyoung Pharmaceutical Co. Ltd	China
		Ceftriaxone	Safe-Tax	50 vials	1344Z183 and 3 other batches in the market	Scot-Edil Advance Research Laboratories	India

			Theoxone - 1g	50 vials	ECFXM24057 and 3 other batches in the market	Theon Pharmaceuticals Ltd	India
			Trox-1	50 vials	NXTIE-011 and 3 other batches in the market	Laborate Pharmaceuticals India Ltd	India
		Cefuroxime	Cefuken DS Syr	20 botlles	34B5411 and 3 other batches in the market	Relax Biotech Pvt Ltd	India
			Exime DS	20 bottles	CKD23007 and 3 other batches in the market	Brussels Laboratories Pvt Ltd	India
			Mexirof 125mg	20 bottles	24B5441and 3 other batches in the market	Relax Biotech Private Limited	India
		Cephalexin	Leocef	20 bottles	86260 and 3 other batches in the market	Laboratory & Allied Ltd	Kenya
		Chloramphenicol	Ivyphenicol Eye Drops	50 bottles	Any 4 batches in the market	B Braun Ltd, Kenya	Kenya
		Ciprofloxacin	Ciprolab	100 tablets	BN 84658 and 3 other batches in the market	Laboratory & Allied Ltd	Kenya
		Cotrimoxazole	Cotricel	20 bottles	BN lco23004 and 3 other batches	Zain Pharma Limited	Kenya
		Doxycycline	Doximar Capsules	100 capsules	Any 4 batches in the market excluding BN BPL 281A	Biopharma Ltd	Kenya
		Flucloxacillin	Dawa Flox Dps	20 bottles	2307144, 2309258, 2401191 and any other batch	Dawa Limited	Kenya
		Gentamycin	Ivygentacin Eye/ Ear Drops	50 bottles	Any 4 batches in the market	B Braun Ltd, Kenya	Kenya
		Metronidazole	Medzol Inj	20 bottles	230970, 230659 & any other 2 batches	Tianjin King York Group Hubei Tian Yao Pharma Co. Ltd	China
			Medzol Tablets	100 tablets	Any 4 batches in the market excluding 230940	Tianjin King York Group Hubei Tian Yao Pharma Co. Ltd	China

			Trogyl	100 tablets	0224088, 1023091 and 2 other batches in the market	Biodeal Laboratories Ltd	Kenya
			Metrosim Tablets	100 tablets	Any 4 batches in the market excluding BN 3835	Africure Pharmaceuticals India Private Limited	India
2.	Analgesics	Ibuprofen	Simfen-200	100 tablets	003367 and 3 other batches in the market	Africure Pharmaceuticals (India)Private Limited	India
			Triofen	20 bottles	LTR23013, L23L002, KL23049, KL23058, KL23046	Zain Pharma Ltd	Kenya
		Aspirin, Paracetamol, Caffeine	APC	100 tablets	Any 4 batches in the market excluding BN 1223038	Biodeal Laboratories Ltd, Kenya	Kenya
			Mara Moja	100 tablets	Any 4 batches excluding batch number 2311024, 2406159	Beta Healthcare International Ltd	Kenya
	Analgesics	Paracetamol	Blink	20 bottles	Any 4 batches in the market excluding BN CS4594005, CS4594004, 2211011	Kamlaamrut Pharmaceutical LLP	India
			Bravemol IV Infusion	20 bottles	BN VTA23001, VTA24017 and 2 other batches in the market	Tawwab Pharma Pvt. Ltd	India
			Febramol	20 bottles	BN 24830357, 24830365 and 2 other batches	Amanta Healthcare Limited	India
			Lumidol	20 bottles	Any 4 batches in the market excluding BN CM4594007, CM4594008, CM4594009	Kamla Amrut Pharmaceutical Llp	India
			Micromol IV	20 bottles	Sample BN R3180430 and 3 other batches in the market	Realcade Life science Pvt Ltd	India
			Painil	20 bottles	Any 4 batches excluding BN 59014, 59114, 59314,58914, 59514, 59614, 59714	Njimia (K) Limited	Kenya
			Paracetamol Infusion	20 bottles	Sample BN 2309223101 and 3 other batches in the market	Shijiazhuang No.4 Pharmaceutical Co. Ltd	China
			Paradol	100 tablets	Sample BN 230117 and 3 other batches in the market	Dinlas Pharma	Kenya

			Paratal	100 tablets	83942, 83834 & any other 2 batches in the market excluding 83835, 83854 and 83855	Laboratory & Allied Ltd	Kenya
			Medimol Suspension	20 bottles	Any 4 batches in the market excluding BN M13016	Medivet Products Ltd	Kenya
			Curamol Suspension	20 bottles	Any 4 batches in the market excluding BN 2211230	Dawa Life Sciences	Kenya
			Paragen	20 bottles	Any 4 batches in the market excluding BN K4290027	Kamlaamrut Pharmaceutical LLP, India	India
			Betamol	20 bottles	Any 4 batches in the market excluding BN 01215PT	Sphinx Pharmaceuticals Ltd	Kenya
3.	Contraceptive	Levonorgestrel	Lydia	100 tablets	Any 4 batches in the market	Naari Pharma Private Ltd, India	India
			Ecee 2	100 tablets	Any 4 batches in the market	Zydus Healthcare Ltd, India	India
			Back Up	100 tablets	Any 4 batches in the market	Acme Formulations Pvt Ltd, India	India
			Unosure 72	100 tablets	Any 4 batches in the market	Akums Drugs & Pharmaceuticals Ltd	India
			Easyplan -2	100 tablets	Any 4 batches in the market	Mortage Laboratories Pvt Ltd	India
			Emcon	100 tablets	Any 4 batches in the market	Renatu Limited	India
		Levonorgestrel & Ethinylestradiol	Femiplan	100 tablets	BN 8169671 and 3 other batches in the market	Mylan Laboratories Ltd	India

3.6. PMS Sample Size

For each of the brands, less than four samples/batch including the complaint batch were collected giving a total sample size of 140 samples. To prevent the collection of extra samples, there was a central real time recording of the collected samples from the field to guide the other team on what to collect.

3.7. Facility Selection

The selection of facilities was based on the distribution list of the complaint batch(es), distribution lists of other batches currently in the Kenyan market excluding the recall batch as provided by the MAH/LTR, as well as the sources of complaints reported to the PPB.

3.8. Substitution Criteria

Facility Substitution: Sample collectors were allowed to substitute sampling outlets by replacing the selected sampling outlet with the nearest facility found in the same region, in any of the following scenarios.

- If the selected sampling outlet was closed or inaccessible
- If the medicines were not available or the dispenser/seller was unwilling to offer
- If the available medicine in the outlet had less than six months shelf life remaining.
- When the stocks available was limited and medicine was critical in saving patients' lives
- When there was a possibility of not getting the necessary minimum quantity of medicines in the collection outlet.

Sample substitution: Sample collectors were allowed to substitute the complaint batch with any other batch of the same brand in the market. In case the brand targeted was not available, sample collectors were allowed to substitute it with other complaint brands of the same API as indicated in Table *2*.

Table 2 Substitution products

Product category	API	Substitutes
Analgesics	Paracetamol	Kendol Tablets, Solumol Injection, Simdol Tablets, Ace Suspension, Medimol Suspension, Paradol Suspension
	Ibuprofen	Profen 200 Tablets
Antibiotics	Amoxicillin & Clavulanic acid	Acinet Dry Syrup, Acinet 1g Tablets, Bactoclav 625 tablets,
	Ampicillin/Cloxacillin	Axylin
	Azithromycin	Zerocin
Contraceptives	Levonorgestrel	Unipill, Norpil
	Levonorgestrel/ Ethinylestradiol	Lydia Fine

3.9. Definition of a sample

To ensure uniformity in the collection of samples, it was necessary to define the attributes that determine a sample. For this survey, a sample comprised a given health product with the same product name, active ingredient, manufacturer, dosage form, unit dose (strength), batch/lot number, collection site, and packaging material.

3.10. Number of units per sample

The survey was for public health interest and the principle of good laboratory practices for pharmaceutical quality control laboratories was followed. It was ensured that the number of dosage units per sample collected was sufficient to allow for:

- Conducting the planned test(s); Minilabs and compendia testing,
- Investigation testing for those out of specification (OOS),
- Retention samples to be used for retesting in the case of dispute.

See Table *1* for the specific quantities collected per sample.

3.11. Management of the PMS quality survey

Table 3 Responsibility matrix

S/N	Activity	Responsibility
1.	Implementation of protocol for PMS of selected medicines	Head PMS
2.	Nomination of samples and data collectors	Head PMS
3.	Training of sample and data collectors	Head PMS
4.	Training on MiniLabs,	PPB QC
5.	Coordination of sample and data collection- field activity	Head PMS
6.	Screening and testing of samples	PMS/QC
7.	Laboratory report writing	PPB QC
8.	Final PMS report writing	PMS
9.	Implementation of regulatory actions	Deputy Director, Product Safety
10.	Dissemination of findings	Deputy Director, Product Safety

3.12. Field Work Preparation

Samples were collected from each of the selected outlets by a designated team of sample and data collectors. A two-day training workshop was held for all personnel involved in sample and data collection, as well as Minilab screening activities. The training covered the use of data and sample collection tools, and the quality survey protocol, including sampling techniques, sample handling, data entry and management, and the use of Minilab screening technologies.

3.13. Sample collection tools

The following tools were used for sample collection.

1. Sample collection form
2. Facility form
3. Product information review form
4. Screening form
5. Excel Aggregation tool

6. Packaging, labeling, transportation and storage tools- (Ziploc plastic bags, envelopes, markers, pens and pencils, masking tapes, sample packing cartons.

3.14. Sample collection logistics

Sample collectors collected samples from each of the identified sampling outlets. The sample collectors used land transport depending on the accessibility of the sampling sites.

3.15. Sample Collection

The sample collection team at each site performed the following functions:

a. Collected samples in their original packaging from the selected outlets or substitute where necessary.
b. Labelled each sample container/package with the unique sample code consisting of the county code, name of the molecule, date of sample collection, and sequential serial number of the sample e.g. NBI/GEM/27.08.2024/005 as indicated below:
    A: County code (as per gazette notice; e.g., NBI for Nairobi)
    B: Product code (e.g. GEM for Gemcitabine Injection)
    C: Date of sample collection (e.g., 27.03.2024)
    D: Three-digit sequential number of the sample. (e.g. 005)
c. The sample labelling was done at the time of sampling to avoid mix-up.
d. Ensured samples collected had at least six (6) months remaining to expiry.
e. Ensured all sample contents were maintained, including package leaflets
f. Recorded sample information details in the sample collection form and facility details in facility form for each sample collected, and also the Excel database. Whenever the required information was not available, it was indicated in the appropriate space on the sample information collection form. Any other relevant observations were recorded in the spaces provided.
g. Packed each sample in special packaging materials provided together with the completed sample collection form and sealed appropriately.
h. Stored samples appropriately in accordance with the manufacturer's instructions.
i. Shipped samples to the PPB main office. Appropriate measures and adequate care were taken to ensure that samples reached the test site (Minilab or confirmatory) without any physical or chemical damage.
j. Wrote a field summary report using the format prepared

3.16. Laboratory analysis of samples

All samples were first verified for their registration status, after which laboratory analysis was conducted.

The analysis adopted a risk-based, three-level testing approach. Level I was visual and physical inspection and product information review, which was done at the sample collection site. Level II was MiniLab testing conducted at two sublevels: Level IIA screening of samples at the PPB regional offices using MiniLab and Level IIB involved verification of MiniLab results at the PPB quality control laboratory. Level III was confirmatory testing, conducted using compendial methods

3.16.1. Level I

All collected samples were subjected to the following tests: physical/visual inspection (registration status, expiry, product packaging, etc.) and product information review, which entailed inspection of the patient information leaflets and other literature inserts. The data was filled in the Product Information Review Form.

Samples determined to be degraded or contaminated at time of collection (which were visually detected at this stage), did not undergo full analytical test but a laboratory analysis report was issued for such indicating compliance status.

3.16.2. Level IIA and IIB

Level IIA: This level involved undertaking the disintegration test and Thin-Layer Chromatography (TLC) using the Minilab. The test results for each sample were recorded on the screening form by the analysts at the PPB regional offices. Once the screening was finalized, all samples with their respective forms attached (Sample Collection Form and screening Form) and TLC plates were stored and archived at the PPB according to the internal policy documents and procedures

Level IIB: The verification testing was conducted by repeating basic tests on the samples previously tested at Level IIA that failed or had a doubtful result. The results were recorded for each sample on the Screening Form. The samples that failed or were doubtful after verification, and 20% of the passed samples, were subjected to confirmatory testing.

A sample was classified as:

a. **Passed** if it conformed to all product information and Minilab tests.

b. **Failed** if it did not conform to at least one of the three tests.
c. **Doubtful** if there were conflicting or inconclusive results for at least one of
    a. the three tests

Molecules that were subjected to Minilab tests include those in Table *4*

Table 4 Molecules subjected to MiniLab screening

Molecules	**Dosage forms**
Amoxicillin	Capsules, tablets, suspensions
Amoxicillin/Clavulanate	Capsules, suspensions
Aspirin/Paracetamol/Caffeine	Tablets
Azithromycin	Tablets, Suspensions
Benzathine Penicillin	Injectables
Ceftriaxone	Injectables
Cefuroxime	Suspensions
Ciprofloxacin	Tablets
Cotrimoxazole	Suspension
Metronidazole	Injectables, Tablets, Suspensions
Paracetamol	Injectables, Tablets, Suspensions

The remaining molecules with no minilab methods were subjected to Raman and/or Near Infrared screening Technologies for Identification testing based on the availability of existing libraries.

3.16.3. Level III: Confirmatory testing with compendial analysis

This level of testing was carried out at the PPB_QC Laboratory and any other PPB-prequalified quality control laboratory. The following criteria was taken into consideration

1. All samples that did not comply at level I and II.
2. All samples which had doubtful results at level II.
3. 20% of all samples that complied at level II.
4. All samples that lacked Minilab protocol.

Samples were analyzed at the Laboratory using methods obtained from official current compendia, i.e., British Pharmacopoeia (BP), United States

Pharmacopoeia, (USP), International Pharmacopoeia and/or authorized manufacturers methods of analysis.

Test parameters conducted on the sampled products are as shown in Table *5*

Table 5 Sample test parameters

Product Brand Name	**INN**	**Dosage Form**	**Test Parameters**
Moximed	Amoxicillin 250mg Capsules	Capsules	ID, Assay, Dissolution,
Doximar	Doxycycline 100mg	Capsules	ID, Assay, Dissolution,
Benzapene 2.4 MU	Benzathine Penicillin 2.4 Mu	Injection	ID, Assay, pH,
Blink	Paracetamol	Injection	ID, Assay, pH,
Bravemol Iv Infusion	Paracetamol	Injection	ID, Assay, pH,
Febramol	Paracetamol	Injection	ID, Assay, pH,
Leocef	Cephalexin	Injection	ID, Assay, pH,
Lumidol	Paracetamol	Injection	ID, Assay, pH,
Medzol Inj	Metronidazole	Injection	ID, Assay, pH,
Micromol Iv	Paracetamol	Injection	ID, Assay, pH,
Paracetamol Infusion	Paracetamol	Injection	ID, Assay, pH,
Paragen	Paracetamol 1% W/V	Injection	ID, Assay, pH,
Safe-Tax	Ceftriaxone	Injection	ID, Assay, pH
Theoxone - 1g	Ceftriaxone	Injection	ID, Assay, pH
Trox-1	Ceftriaxone	Injection	ID, Assay, pH
Almox	Amoxicillin	Suspension	ID, Assay,
Cefuken Ds Syr	Cefuroxime	Suspension	ID, Assay,
Cloxam	Ampicillin/Cloxacillin	Suspension	ID, Assay,
Cotricel	Cotrimoxazole	Suspension	ID, Assay,
Dawa Flox DPS	Flucloxacillin	Suspension	ID, Assay,
Exime DS	Cefuroxime	Suspension	ID, Assay,
Izzithree	Azithromycin	Suspension	ID, Assay,
Mexirof 125mg	Cefuroxime	Suspension	ID, Assay,
Painil	Paracetamol	Suspension	ID, Assay,
Triofen	Ibuprofen Oral Suspension (100mg/ 5ml)	Suspension	ID, Assay,
Zimycin	Azithromycin	Suspension	ID, Assay,
Medimol	Paracetamol	Suspension	ID, Assay,
Curamol Suspension	Paracetamol	Suspension	ID, Assay,
Azithrosafe	Azithromycin	Suspension	ID, Assay,

Product Brand Name	INN	Dosage Form	Test Parameters
C-Azi	Azithromycin	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Ciprolab	rofloxacin	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Femiplan	Levonorgestrel And Ethinylestradiol	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Kemoxyl DT	Amoxicillin DT 250mg	Dispersible Tablet	ID, Assay, Dissolution, Friability, Disintegration
Medzol	Metronidazole	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Metrosim	Metronidazole 200mg	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Paradol	Paracetamol	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Paratal	Paracetamol	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Rapiclav 312.5 DT	Amoxicillin & Clavulanic Acid	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Shalzin	Azithromycin	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Simfen-200	Ibuprofen 200mg	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Trogyl	Metronidazole	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Betamol	Paracetamol 500mg	Tablet	ID, Assay, Dissolution, Friability, Disintegration
APC	Asprin, Paracetamol, Caffeine	Tablet	ID, Assay, Dissolution, Friability, Disintegration
Ivygentacin	Gentamycin Eye/Ear Drops	Eye/Ear Drops	ID, Assay, pH,
Ivyphenicol	Chloramphenicol Eye Drops	Eye/Ear Drops	ID, Assay, pH,
Lydia	Levonorgestrel	Tablet	ID, UOC, Dissolution, Friability, Disintegration
Ecee 2	Levonorgestrel	Tablet	ID, UOC, Dissolution, Friability, Disintegration
Back Up	Levonorgestrel	Tablet	ID, UOC, Dissolution, Friability, Disintegration
Unosure 72	Levonorgestrel	Tablet	ID, Uoc, Dissolution, Friability, Disintegration

In cases of OOS where the official compendia were used, the laboratory carried out re-testing of the sample using validated manufacturer's methods of analysis, and the validated OOS results were notified immediately to the PMS Department for regulatory action.

In case of contested test results at the PPB laboratory, joint re-testing with the LTR/manufacturer representative was carried out at the PPB QCL or retest at NQCL/PPB-prequalified lab at the LTR/manufacturer cost.

A Certificate of Analysis (COA) or Laboratory analysis report (LAR) that entailed a summary of the results obtained was issued for each sample analyzed. In addition to the COA, an analysis report was compiled and provided by PPB QCL.

For substituted products, the test parameters were conducted based on the dosage form as per Table 6

Table 6 Test parameters for substituted products

Dosage Form	**Test parameters**
Capsules	ID, Assay, Dissolution
Injection	ID, Assay, PH,
Suspension	ID, Assay,
Tablet	ID, Assay, Dissolution, Friability, Disintegration
Eye/Ear Drops	ID, Assay, pH

3.17. Fieldwork Preparation and Implementation

To ensure the success of a robust and comprehensive post-market surveillance (PMS) field survey, thorough preparation and structured implementation are critical. A dedicated team of data and sample collectors were carefully selected and assigned to carry out systematic sampling across pre-identified health facilities nationwide.

The preparation phase began with intensive training for all assigned personnel. The training covered the PMS protocol, including detailed instructions on proper sampling techniques, accurate and consistent data collection procedures, and the use of standard documentation tools. Furthermore, the team had hands-on induction sessions on the operation and application of field-based screening technologies. These included portable devices such as Minilabs, which were essential for preliminary quality assessment of medicines in the field.

To maintain consistency and ensure data reliability, predesigned and standardized sample collection tools and templates were employed during fieldwork. The sample collection exercise was conducted over a six-day period, during which the teams visited the designated facilities and collected pharmaceutical product samples, alongside relevant metadata.

Following the sample collection phase, a subsequent five-day sample screening process took place at the regional offices and Pharmacy and Poisons Board QC Laboratory. During this stage, collected samples were subjected to preliminary quality screening using the aforementioned technologies, and screening results were documented accordingly.

For efficient and wide-reaching coverage, the fieldwork was executed by five mobile teams. Each team was composed of three trained personnel responsible for both data entry and sample collection. These teams operated concurrently, with each team tasked with collecting ten samples per day, thus ensuring a systematic and comprehensive sampling across all selected sites.

3.18. Data Analysis, Interpretation, and Dissemination

3.18.1. Data Quality Assurance

The quality of data was assured through the development of a protocol for the activity and provision of standardized training to the samples and data collectors and applying standardized tools for data and samples collection. The teams carrying out data and sample collection were supervised by a central coordination team. Screening and compendial testing of the samples were undertaken using the laboratory SOPs and guidelines.

3.18.2. Data Analysis and Interpretation

The results of the analysis of samples were classified as either “complies or does not comply” with the specifications of the test parameters analysed. Samples that did not comply were further disaggregated as unregistered, substandard, or falsified. The WHO’s definition was used to classify the HPTs as “Substandard or

falsified", while the PPB policy on registration of HPTs was applied in the determination of registration status of the HPTs.

4. RESULTS

4.1. Samples collected

One hundred and forty (140) samples were collected from 60 facilities. These comprised both private (5) 8.33% facilities and public facilities (55) 91.66% spread across 22 of the 47 counties in Kenya. As part of the field activity, facilities were audited for temperature and relative humidity monitoring in line with Good Storage Practices for HPTs.

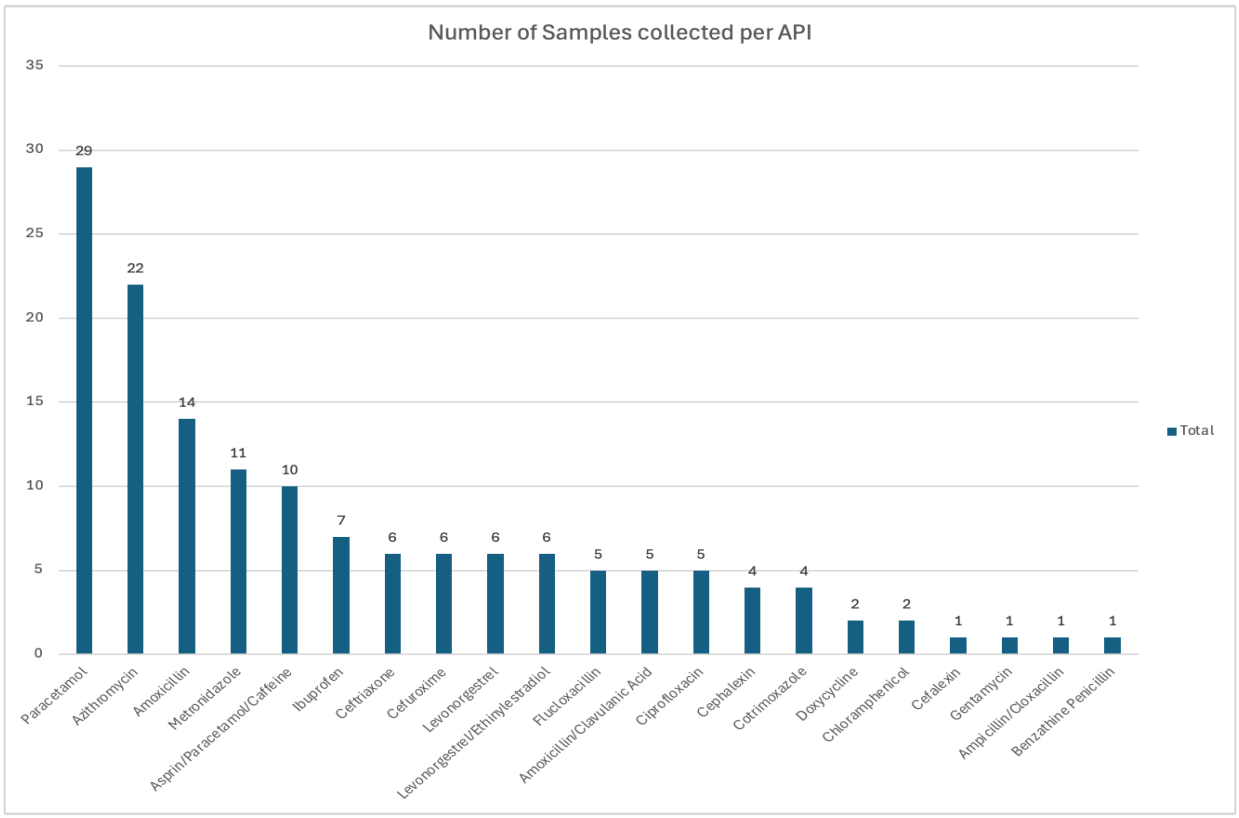

Figure 1 Distribution of samples collected

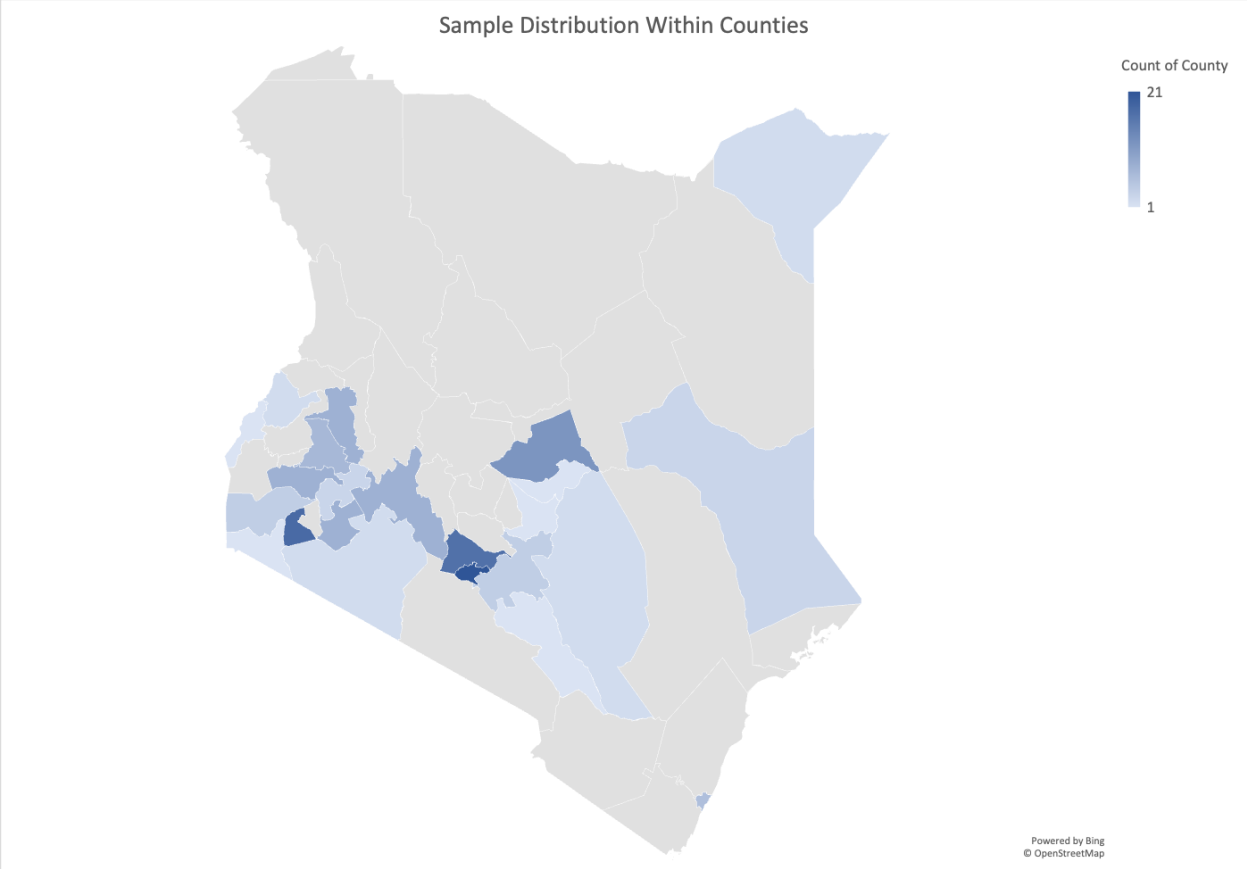

Figure 2 : Sample distribution within counties

The table below provides a detailed comparison between the planned sampling targets (as per the protocol) and the actual samples collected during the surveillance exercise:

Table 7 Planned sampling targets (as per the protocol) and the actual samples collected

API/Product Category	Planned Target (Number of Batches)	Samples Actually Collected	Achievement Rate	Variance	Primary Reasons for Variance
Antibiotics					
Amoxicillin	12 (4 batches × 3 brands)	11	91.7%	-1	1 batch unavailable in target regions
Amoxicillin/ Clavulanic Acid	4 (4 batches × 1 brand)	5	125%	+1	Additional substitution product collected
Ampicillin/ Cloxacillin	4 (4 batches × 1 brand)	3	75%	-1	Limited distribution in sampled areas
Azithromycin	20 (4 batches × 5 brands)	16	80%	-4	2 brands unavailable, 2

API/Product Category	Planned Target (Number of Batches)	Samples Actually Collected	Achievement Rate	Variance	Primary Reasons for Variance
					batches out of stock
Benzathine Penicillin	4 (4 batches × 1 brand)	1	25%	-3	Supply chain issues, high demand product
Ceftriaxone	12 (4 batches × 3 brands)	8	66.7%	-4	Hospital-only products, access limitations
Cefuroxime	12 (4 batches × 3 brands)	9	75%	-3	Seasonal availability issues
Cephalexin	4 (4 batches × 1 brand)	6	150%	+2	Multiple substitution products collected
Chloramphenicol	4 (4 batches × 1 brand)	2	50%	-2	Specific formulation not available
Ciprofloxacin	4 (4 batches × 1 brand)	5	125%	+1	Additional batch found during collection
Cotrimoxazole	4 (4 batches × 1 brand)	4	100%	0	Target fully met
Doxycycline	4 (4 batches × 1 brand)	3	75%	-1	Import delays affecting supply
Flucloxacillin	4 (4 batches × 1 brand)	6	150%	+2	Multiple facilities had this product
Gentamycin	4 (4 batches × 1 brand)	1	25%	-3	Specialty product, limited availability
Subtotal Antibiotics	**96**	**81**	**84.4%**	**-15**	
Metronidazole					
Metronidazole (Various)	16 (4 batches × 4 brands)	14	87.5%	-2	One brand discontinued, limited batch availability
Subtotal Metronidazole	**16**	**14**	**87.5%**	**-2**	
Analgesics					
Ibuprofen	8 (4 batches × 2 brands)	7	87.5%	-1	One batch expired at collection sites
Asprin/ Paracetamol/ Caffeine (APC)	8 (4 batches × 2 brands)	9	112.5%	+1	Additional substitution product collected
Paracetamol (Various)	52 (4 batches × 13 brands)	29	55.8%	-23	Multiple brands unavailable, supply chain disruptions
Subtotal Analgesics	**68**	**45**	**66.2%**	**-23**	
Contraceptives					
Levonorgestrel	20 (4 batches × 5 brands)	11	55%	-9	Sensitive product, limited shelf availability
Levonorgestrel/ Ethinylestradiol	4 (4 batches × 1 brand)	4	100%	0	Target fully met

API/Product Category	Planned Target (Number of Batches)	Samples Actually Collected	Achievement Rate	Variance	Primary Reasons for Variance
Subtotal Contraceptives	**24**	**15**	**62.5%**	**-9**	
GRAND TOTAL	**204**	**140**	**68.6%**	**-64**	

4.2. Storage conditions

A total of 22 (36.67%) facilities monitored both temperatures and humidity, while 7(11.67%) facilities did not monitor humidity but monitored temperature. A total of 31 (51.67%) facilities did not monitor humidity and temperature of their storage areas.

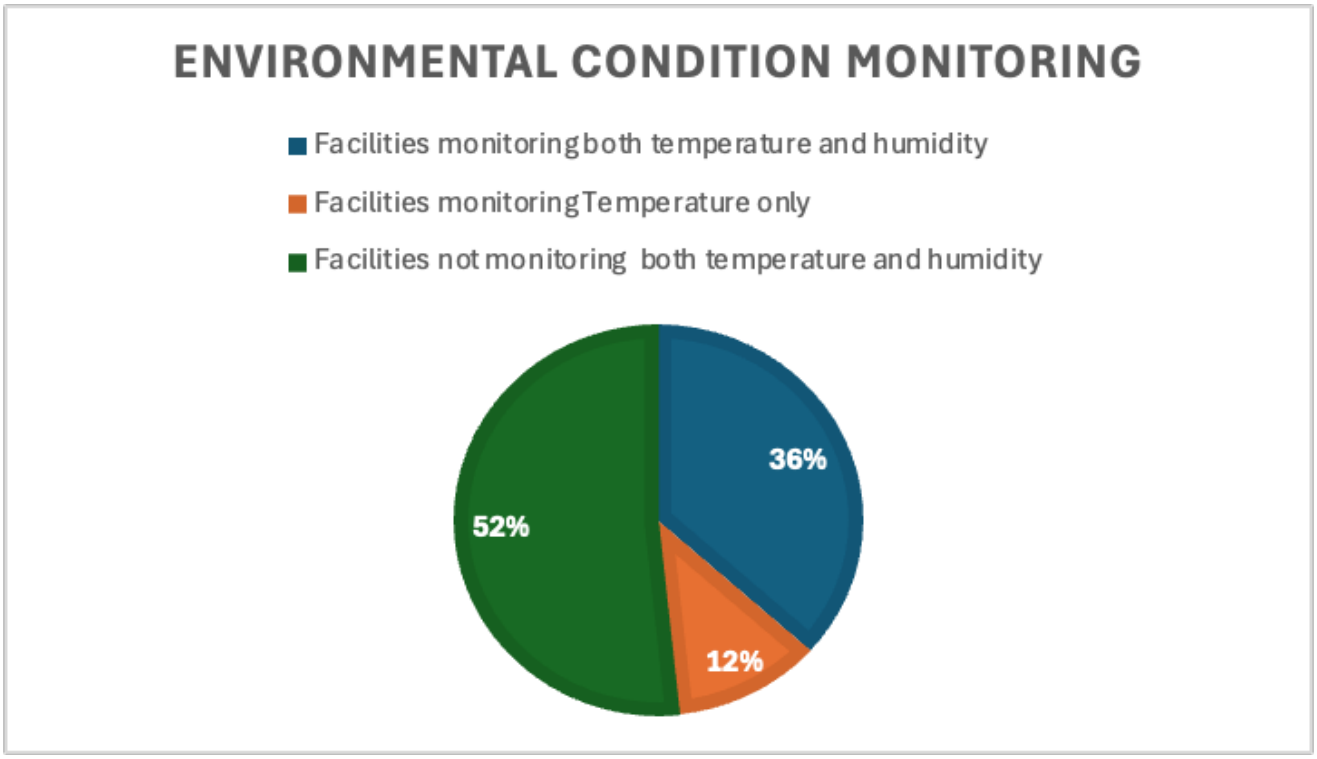

Figure 3 Environmental condition monitoring

4.3. Physical/Visual Screening

All the one hundred and forty samples were subjected to physical/visual screening and they complied with the specifications.

4.4. Field screening using Minilab technique

One hundred and ten (110) out of 140 samples representing 78.57 % underwent field screening minilab (Level I&II). One hundred and nine samples complied while one (1) sample (Paradol suspension batch no. 240831) failed on appearance (crystals observed).

4.5. Compendial testing results by API

The table below summarizes the compendial testing results organized by Active Pharmaceutical Ingredient (API), showing the number of samples tested, passed, failed, and corresponding pass rates:

Table 8 Compendial testing results

Active Pharmaceutical Ingredients	Total Samples Tested	Samples Complied	Samples Failed	Pass Rate	Key Failure Products
Azithromycin	4	2	2	50%	Izzithree Suspension, Zimycin Suspension
Levonorgestrel	6	6	0	100%	-
Paracetamol	15	14	1	93.3%	Medimol Suspension
Amoxicillin	2	2	0	100%	-
Amoxicillin/ Clavulanic Acid	1	1	0	100%	-
Cefuroxime	2	1	1	50%	Cefuken DS
Ciprofloxacin	1	1	0	100%	-
Metronidazole	3	3	0	100%	-
Ceftriaxone	2	2	0	100%	-
Ibuprofen	4	4	0	100%	-
Cotrimoxazole	1	1	0	100%	-
Flucloxacillin	3	3	0		
Doxycycline	1	1	0		
Cephalexin	1	1	0		
Total/Average	**46**	**42**	**4**	**91.3%**	

Note: Total samples tested (46) underwent confirmatory testing

The table below summarizes the compendial testing results organized by product formulation (dosage form):

Table 9 : Compendial testing results organized by product formulation

Formulation Type	Total Samples Tested	Samples Complied	Samples Failed	Pass Rate	Key Failed Products
Tablets	22	22	0	100%	-
Suspensions	18	14	4	72.2%	Izzithree Suspension, Zimycin Suspension, Medimol Suspension, Cefuken DS
Injections	4	4	0	100%	-
Capsules	2	2	0	100%	-
TOTAL	**46**	**42**	**4**	**91.3%**	

4.5.1. Analgesics

4.5.1.1. Paracetamol Infusion

The following tests were carried out:

Test	Reference	Specifications
Identification by HPLC	In-House	The retention time of the major peak in the chromatogram obtained with the Sample preparation corresponds to that in the chromatogram of the Standard preparation as obtained in the Assay
Identification by UV (PDA)	In-House	The UV spectrum of the Sample solution exhibits maxima and minima only at the wavelength as that of a similar solution of Paracetamol reference Standard.
Extractable Volume	In-House	Not less than the stated nominal volume of the container (100 ml)
pH	In-House	4.00 to 6.00
Assay by HPLC	In-House	90.0% to 110.0% of the stated amount
Sterility	In-House	Sterile

The two (2) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as shown in Table 8.

Table 10 Paracetamol Infusion Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extractable Volume	pH	Assay
		County	Facility							
1.	NKR/PCTI/26.06.2025/014	Nakuru	Molo Sub County Hospital	Lumidol	KamlaAmrut Pharmaceutical LLP, India	CM2595005	Complies	100ml	5.73	108.1 %
2.	BSA/PCTI/28.06.2025/040	Busia	Zemela	Axapara	Axa Parenterals Ltd, India	DD50179	Complies	101.0ml	5.8	103.4 %

4.5.1.2. Paracetamol Suspension

The following tests were carried out:

Test	Compendia	Specifications
Identification by TLC	BP 2024	The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2)
Identification by HPLC	BP 2024	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.
Deliverable Volume	BP 2024	The average Volume obtained is not less than 100% and the Volume of no container is less than 95% of the Volume declared on the labeling.
Assay by HPLC	BP 2024	95.0% to 105.0% of the stated amount.

Four (4) out of five (5) Paracetamol Suspension samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as illustrated in Table 9. One sample failed to comply with the specifications for the assay test.

Table 11 Paracetamol Suspension Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable Volume	Assay
		County	Facility						
1.	NAI/PCTS/ 26.06.2025 /011	Nairobi	Transchem Pharmaceutical Limited	Curamol	Dawa Ltd	2504074	Complies	96.1%	101.9%
2.	HBY/PCTS/ 28.06.2025 /039	Kisumu	Victoria Healthcare Ltd	Curamol	Dawa Ltd	2411003	Complies	97.5%	101.0%
3.	KSM/PCTS/ 28.06.2025 /037	Kisumu	Kentons Ltd	Betamol	Sphinx Pharmaceutical Ltd	02583P	Complies	95.4%	99.8%
4.	KMB/PCTS /27.06.202 5/031	Kiambu	Upesi Pharmacy	Betamol	Sphinx Pharmaceutical Ltd	02583P	Complies	97.1%	96.2%
5.	UGS/PCTS/ 27.06.2025 /021	Uasin Gishu	Uasin Gishu County Referral Hospital	Medimol	Medivet Products Ltd	M13058	Complies	95.4%	88.0%

4.5.1.3. Paracetamol Tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP43-NF38	The retention times of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay
Dissolution Test by UV-Vis Spectrophotometry	USP43-NF38	S1 ≥75% (Q) of the stated amount Paracetamol is dissolved in dissolution medium in 30 minutes.
Mass Spectrometry	USP43-NF38	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight

Test	Compendia	Specifications
Weight Variation	USP43-NF38	L1 Maximum acceptance value for 10 units - not more than 15
Assay by HPLC	USP43-NF38	90.0% to 110.0% of the stated amount

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as illustrated in Table 10

Table 12 Paracetamol Tablets Sample Details and Analysis Results

	Sample Code	Sampled from County	Facility	Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
1.	MRU/PCTT/27.06.2025/010	Meru	MetaMeta Chemists	Paradol	Dinlas Pharma (Africa) Ltd	250061	Complies	95.2%	97.9%

4.5.1.4. Ibuprofen Suspension

The following tests were carried out:

Test	Compendia	Specifications
Identification by Infrared Spectrophotometry (FTIR)	BP 2024	The infrared absorption spectrum of the reside is concordant with reference spectrum of ibuprofen (RS 186).
Deliverable volume	BP 2024	S1 ≥75% (Q) of the stated amount Paracetamol is dissolved in dissolution medium in 30 minutes.

Test	Compendia	Specifications
pH	BP 2024	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight
Assay by HPLC	BP 2024	90.0% to 110.0% of the stated amount

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 11.

Table 13 Ibuprofen Suspension Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	pH	Assay
		County	Facility							
1.	MRU/IBFS/28.06.2025/019	Meru	Transwide Pharmaceuticals Ltd	Triofen	Zain Pharma Ltd	L25E025	Complies	100ml	6.09	95.4%
2.	NAI/IBFS/26.06.2025/019	Nairobi	Prayosha Healthcare	Triofen	Zain Pharma Ltd	L24L045	Complies	60.0 ml	6.06	101.8%
3.	KSI/IBFS/26.06.2025/019	Kisii	Transwide Pharmaceuticals- Kisii	Triofen	Zain Pharma Ltd	L25E023	Complies	100.0 ml	6.08	100.0%
4.	KMB/IBFS/27.06.2025/037	Kiambu	Transwide Pharmaceuticals-Thika	Triofen	Zain Pharma Ltd	L25E025	Complies	100.0 ml	6.31	97.7%

4.5.1.5. Paracetamol, Caffeine, and Aspirin Tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP43-NF38	The retention times of the major peaks of the sample solution correspond to those of the Standard solution as obtained in the Assay.
Dissolution by HPLC	USP43-NF38	S1 80% of the stated amounts of Paracetamol, Caffeine and Aspirin is dissolved in Dissolution medium in 60 minutes. S2 Average of 12 units (S1+S2) is equal or greater than Q (75%) and no unit is less than Q-15% (60%)
Mass Uniformity	USP43-NF38	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight.
Weight variation	USP43-NF38	L1 Maximum acceptance value for 10 units - not more than 15.
Assay by HPLC	USP43-NF38	90.0% to 110.0% of the stated amounts

The samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 12.

Table 14 Paracetamol Tablets Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Assay
		County	Facility					
1.	KMB/PCTT/27.06.2025/022	Kiambu	Sizwe Pharmaceuticals Ltd	Mara Moja	Beta Healthcare International Ltd	2409180	Complies	Paracetamol: 102.8% Caffeine: 100.1% Aspirin: 102.1%

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Assay
		County	Facility					
2.	KSI/APC/26.06.2025/016	Kisii	Goodlife Pharmacy	Mara Moja	Beta Healthcare International Ltd	2408014	Complies	Paracetamol: 99.6% Caffeine: 102.1% Aspirin: 100.6%
3.	NAI/APC/26.06.2025/014	Nairobi	Transwide Pharmaceuticals Ltd	A.P.C	Biodeal Laboratories Ltd	0624133	Complies	Paracetamol: 101.0% Caffeine: 104.3% Aspirin: 96.2%
4.	KSI/APC/26.06.2025/021	Kisii	Transwide Pharmaceuticals-Kisii	A.P.C	Biodeal Laboratories Ltd	1124086	Complies	Paracetamol: 98.47% Caffeine: 97.09% Aspirin: 98.75%
5.	NKR/APC/26.06.2025/019	Nakuru	Supreme Pharmacy Ltd	A.P.C	Biodeal Laboratories Ltd	0424008	Complies	Paracetamol: 95.26% Caffeine: 95.49% Aspirin: 96.06%
6.	NRK/APC/25.06.2025/002	Narok	Jaslim Pharmacy Ltd	A.P.C	Biodeal Laboratories Ltd	1024003	Complies	Paracetamol: 101.8% Caffeine: 101.5% Aspirin: 96.7%
7.	NKR/APC/26.06.2025/032	Nakuru	Metropolitan Chemists Ltd	Mara Moja	Beta Healthcare International Ltd	2401074	Complies	Paracetamol: 97.9% Caffeine: 99.6% Aspirin: 101.0%

4.5.2. Antibiotics

4.5.2.1. Amoxicillin DT

The following tests were carried out:

Test	Compendia	Specifications
Identification by TLC	USP 43 NF 38	The RF value of the principal spot of the Sample solution corresponds to that of the Standard solution.

Test	Compendia	Specifications
Disintegration	USP 43 NF 38	All the six tablets disintegrate within 3 minutes in water
Dissolution by HPLC.	USP 43 NF 38	S1 ≥ 80% (Q) of the stated amount of Amoxicillin is dissolved in dissolution medium in 30 minutes
Mass Uniformity	USP 43 NF 38	Not more than two units deviate by 5.0% and none by 10.0% from the average weight
Weight Variation.	USP 43 NF 38	L1 Maximum acceptance value for 10 units- not more than 15.
Assay by HPLC.	USP 43 NF 38	90.0% to 110.0% of the stated amount.

The two (2) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as shown in Table 13.

Table 15 Amoxicillin DT tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	MCK/AMXT/24.06.2025/001	Machakos	Barach Chemist	Kemoxyl DT	Laboratory & Allied Ltd	88525	Complies	88%	99.1%

4.5.2.2. Amoxicillin Capsules

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP 43 NF 38	The retention time of the major peak of the sample solution corresponds to that of the Standard solution as obtained in the Assay
Disintegration	USP 43 NF 38	All the six capsules disintegrate within 3 minutes in water
Dissolution by HPLC.	USP 43 NF 38	S1 ≥ 80% (Q) of the stated amount of Amoxicillin is dissolved in dissolution medium in 60 minutes
Mass Uniformity	USP 43 NF 38	Not more than two units deviate by 7.5% and none by 15.0% from the average weight
Weight Variation.	USP 43 NF 38	L1 Maximum acceptance value for 10 units- not more than 15.
Assay by HPLC.	USP 43 NF 38	90.0% to 120.0% of the stated amount.

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 14.

Table 16 Amoxicillin Capsules Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution By HPLC	Assay
		County	Facility						
1.	KSM/AMXT/28.06.2025/034	Kisumu	Kentons Ltd	Moximed	Medivet Products Ltd	P3738	Complies	88.2%	96.1%

4.5.2.3. Amoxicillin and Potassium Clavulanate Samples

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP43-NF38	The retention time of the major peak of the sample solution corresponds to those of the standard solution as obtained in the Assay
Disintegration	USP43-NF38	All six tablets disintegrate within 30 minutes water
Dissolution	USP43-NF38	1 ≥ 85% (Q) Of the stated amount of Amoxicillin Trihydrate is dissolved in dissolution medium in 30 minutes. ≥ 80% (Q) Of the stated amount of Clavulanic Acid is dissolved in dissolution medium in 30 minutes
Mass Uniformity	USP43-NF38	Not more than two units deviate by 5% and none by 10.0% from the average weight.
Weight Variation	USP43-NF38	L1 Maximum Acceptance Value for 10 units is not more than 15
Assay by HPLC.	USP43-NF38	90.0% to 120.0% of the stated amount

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 15.

Table 17 Amoxicillin and Clavulanic Acid Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	NDI/AMXT/27.06.2025/028	Nandi	Berur Pharmacy	Bactoclav	Micro-Labs Ltd	BABBV 0166	Complies	Amoxicillin: 97.0% Clavulanic Acid: 101.3%	Amoxicillin: 99.4% Clavulanic Acid: 102.3%

4.5.2.4. Flucloxacillin Powder for Oral Solution

The following tests were carried out

Test	Compendia	Specifications
Identification by TLC	BP 2024	The principal spot in the chromatogram obtained with solution (1) is similar in position, colour and size to that in the chromatogram obtained with solution (2). The test is not valid unless the chromatogram obtained with solution (3) shows three clearly separated spots.
Deliverable volume	BP 2024	The average volume obtained is not less than 100% and the Volume of no container is less than 95% of the volume declared on the labeling.
pH	BP 2024	Between 4.0 to 7.0.
Assay by HPLC	BP 2024	80.0% to 120.0% of the stated amount

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as illustrated in Table 16.

Table 18 Flucloxacillin Oral solution

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	pH	Assay
		County	Facility							
1.	TNT/FLXS/ 27.06.2025/ 009	Tharaka-Nithi	Chuka Afya	Dawa Flox DPS	Dawa Limited	2407211	Complies	102%	6.3	95.8%
2.	BGM/FLXS /28.06.2025 /041	Bungoma	Bungoma West Hospital	Dawa Flox DPS	Dawa Limited	2406053	Complies	101.0%	6.3	95.1%

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	pH	Assay
		County	Facility							
3.	MDR/FLXS /26.06.2025 /002	Mandera	Mandera Drug Mart	Dawa Flox DPS	Dawa Limited	2411081	Complies	100%	6.4	96.6%

4.5.2.5. Azithromycin 500mg Tablet

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP 43 BF 38	The retention time of Azithromycin peak in the chromatogram of the Sample solution corresponds to that of the Standard solution as obtained in the Assay
Identification By Infrared Spectrophotometry (FTIR).	USP 43 BF 38	The Infrared absorption spectrum of the Sample is concordant with that of the Azithromycin reference Standard.
Dissolution by HPLC	USP 43 BF 38	S1 ≥ 80% (Q) of the stated amount of Azithromycin is dissolved in the dissolution medium in 30 minutes.
Mass Uniformity	USP 43 BF 38	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight.
Weight Variation	USP 43 BF 38	L1 Maximum acceptance value for 10 units- not more than 15.
Assay by HPLC	USP 43 BF 38	90.0% to 110.0% of the stated amount.

The samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 17

Table 19 Azithromycin tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	KTU/AZTT/26.06.2025/007	Kitui	Kasue Chemist	Shalzin	Shalina Laboratories Pvt Ltd	4374129	Complies	98.8%	98.1%
2.	MDR/AZTT/26.06.2025/001	Mandera	Mandera Drug Mart	C-Azi	Innova Captab Ltd	G307E4011	Complies	95.7%	98.4%

4.5.2.6. Azithromycin 200mg suspension

Test	Compendia	Specifications
Identification test by HPLC.	USP 43 NF 38	The retention time of the Azithromycin peak of the Sample solution corresponds to that of the standard solution as obtained in the Assay.
Deliverable Volume.	USP 43 NF 38	The average Volume obtained is not less than 100% and the Volume of no container is less than 95% of the Volume declared on the labeling.
pH	USP 43 NF 38	Between 8.5 to 11.0.
Assay by HPLC	USP 43 NF 38	90.0% to 110.0% of the stated amount.

The samples failed to comply with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 18.

Table 20 Azithromycin suspension

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	pH	Assay
		County	Facility							
1.	NDI/AZTS/27.06.2025/031	Nandi	Chebarbar Chemist	Izzithree	Biopharma Ltd	BPL 915A	Complies	100%	8.0	84.0%
2.	MSA/AZTS/30.06.2025/005	Mombasa	Pharmaken Ltd	Zimycin	Saga Lifesciences limited	ZIUO22404	Does not comply	100%	10%	80.7%

4.5.2.7. Ceftriaxone Injection

The following tests were carried out:

Test	Compendia	Specifications
Identification A By Infrared Spectrophotometry (FTIR)	USP 43 NF 38	The Infrared absorption spectrum obtained with the Sample is concordant with the spectrum of Ceftriaxone Sodium reference Standard.
Identification B by HPLC	USP 43 NF 38	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.
Identification By Infrared Spectrophotometry (FTIR).	USP 43 NF 38	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.
Mass Uniformity	USP 43 NF 38	Between 6.0 and 8.0.
Weight Variation	USP 43 NF 38	L1 Maximum acceptance value for 10 units- not more than 15.

Test	Compendia	Specifications
Assay by HPLC	USP 43 NF 38	90.0% to 110.0% of the stated amount.
Sterility	USP 43 NF 38	Sterile

The two (2) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 19.

Table 21 Ceftriaxone injection

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Assay
		County	Facility					
1.	KMB/CFTI/27.06.2025/024	Kiambu	Sizwe Pharmaceuticals Ltd	Safe-Tax	Syner-Med Pharmaceuticals (K) Ltd	13425Z049	Complies	98.1%
2.	HBY/CFTI/27.06.2025/031	Homa Bay	Medeocare Pharmacy	Theoxone	Theon Pharmaceuticals Ltd	ECFXM25022	Complies	95.1%

4.5.2.8. Cefuroxime Suspension

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP 43 NF 38	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.

Test	Compendia	Specifications
Deliverable Volume	USP 43 NF 38	The average Volume obtained is not less than 00% and the Volume of no container is less that 95% of the Volume declared on the labeling.
pH	USP 43 NF 38	Between 3.5 to 7.0
Assay by HPLC	USP 43 NF 38	90.0% to 110.0% of the stated amount

The sample failed to comply with the specifications for the Assay tests performed as per the requirements of the appropriate compendia as illustrated in Table 20.

Table 22 Cefuroxime suspension

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	Assay
		County	Facility						
1.	NAI/CFXS/26.06.2025/005	Nairobi City	Transchem Pharmaceutical Limited	Cefuken DS	Relax Biotech Pvt Ltd	44B5411	Complies	118.8%	87.6%

4.5.2.9. Cefuroxime Tablet

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP43-NF 38	The retention times of the major peak for Cefuroxime Axetil diastereomers A and B in the chromatogram of the Sample Solution correspond to those of the Standard Solution as obtained in the Assay.

Test	Compendia	Specifications
Disintegration	USP43-NF 38	All six tablets disintegrate within 30 minutes in water
Dissolution by UV-Vis Spectrophotometry.	USP43-NF 38	S1: After 15 Minutes ≥55% of the stated amount of Cefuroxime is dissolved in dissolution medium in 15 minutes. S1: After 45 Minutes ≥ 75% of the stated amount of Cefuroxime is dissolved in dissolution medium in 45 minutes.
Mass Uniformity	USP43-NF 38	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight.
Weight variation	USP43-NF 38	L1 Maximum acceptance value for 10 units is not more than 15
Assay by HPLC	USP43-NF 38	90.0% to 110.0% of the stated amount

The sample failed to comply with the specifications for the Assay tests performed as per the requirements of the appropriate compendia as illustrated in Table 21.

Table 23 Cefuroxime tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	MRU/DXY/28.06.2025/014	Meru	Daima Dispensing Chemist	Doximar Capsules	Biopharma Ltd	BPL800A	Complies	99.3%	90.4%

4.5.2.10. Doxycyline Capsules

The following tests were carried out:

Test	Compendia	Specifications
Identification test A by Thin Layer Chromatography (TLC).	BP 2024	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.
Identification test B by HPLC.	BP 2024	In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).
Dissolution by UV-Vis Spectroscopy.	BP 2024	S1 ≥ 80% (Q) of the stated amount of Doxycycline is dissolved in 30 minutes.
Mass uniformity.	BP 2024	Not more than two capsules deviate by 10.0% and none by 20.0% from the average tilling
Assay by HPLC.	BP 2024	90.0% to 110.0% of the stated amount.

The two (2) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 22.

Table 24 Doxycycline capsules

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	MSA/CFXT/01.07.2025/008	Mombasa	Pharmaken Ltd	Cefuken DS	Globela Pharma Pvt. Ltd	GLT25033A	Complies	85.4%	96.2 %

4.5.2.11. Metronidazole Suspension

The following tests were carried out:

Test	Compendia	Specifications
Identification By HPLC.	USP43-NF38	The retention time of the major peak in the chromatogram of the Sample preparation corresponds to that in the chromatogram of the Standard preparation as obtained in Assay
Container content	USP43-NF38	F38 As average volume should not be less than 10% and no unit is less than 95%
pH	In-House	Between: 4.5 to 7.0
Assay by HPLC	USP43-NF38	90.0% to 110.0% of the stated amount.

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 23.

Table 25 Metronidazole solution

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	Assay
		County	Facility						
1.	KMB/MTZS/27.06.2025/033	Kiambu	Daima Dispensing Chemist	Trogyl	Biodeal Laboratories Ltd	225051	Complies	101.7%	90.4%

4.5.2.12. Metronidazole Tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification A by UV-Vis Spectrophotometry	USP43-NF38	The UV absorption spectrum of the Sample preparation is concordant with that of Standard preparation.
Identification by HPLC.	USP43-NF38	The retention time of the major peak in the Sample solution corresponds to that of the Standard solution, as band in the Asay.
Dissolution Test by UV-Vis Spectrophotometry	USP43-NF38	SI ≥ 85% (Q) of the stated amount Metronidazole is dissolved in dissolution medium in 60 minutes.
Mass Uniformity	USP43-NF38	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight.
Weight Variation	USP43-NF38	**L1** Maximum acceptance value for 10 units - not more than 15.
Assay by Titration.	USP43-NF38	90.0% to 110.0% of the stated amount.

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 24.

Table 26 Metronidazole tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	BMT/MTZT/25.06.2025/008	Bomet	Brunet Pharmacy	Amizol-400	Biopharma Ltd	BPL 763A	Complies	99.4%	98.6%
2.	KSI/METT/26.06.2025/014	Kisii	Jacks Pharmacy	Medzol-400	Shanxi Xinyitong Pharmaceutical Co., Ltd	2410108	Complies	95.4%	90.4%

4.5.2.13. Ciprofloxacin Tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC.	USP43-NF38	The retention time of the major peak in the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
Dissolution Test by UV-Vis Spectrophotometry	USP43-NF38	S1 ≥85% (Q) of the stated amount of Ciprofloxacin is dissolved in dissolution medium in 30 minutes
Mas Uniformity	USP43-NF38	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight.
Weight Variation	USP43-NF38	L1 Maximum acceptance value for 10 units – not more than 15.
Assay by Titration.	USP43-NF38	90.0% to 110.0% of the stated amount.

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 25.

Table 27 Ciprofloxacin tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Dissolution	Assay
		County	Facility						
1.	UGS/CPFT/27.06.2025/024	Uasin Gishu	Ziwa Sub County Hospital	Ciprolab	Laboratory & Allied Ltd	87513	Complies	91.8%	99.6%

4.5.2.14. Cotrimoxazole Suspension

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC.	USP43-NF38	The retention time of the major peak in the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
Deliverable Volume	USP43-NF38	Not less than the stated nominal volume of the container (100ml)
pH.	USP43-NF38	Between 5.0 to 6.0
Assay by HPLC.	USP43-NF38	90.0% to 110.0%

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 26.

Table 28 Cotrimoxazole suspension

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	Assay
		County	Facility						
1.	KMB/CTXS/27.06.2025/026	Kiambu	Pharma & Allied Ltd	Cotricel	Zain Pharma Ltd	L25C035	Complies	99.0ml	Sulfamethoxazone: 100.3% Trimethoprim: 97.3%

4.5.2.15. Cephalexin Suspension

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC.	USP43-NF38	The retention time of the major peak in the chromatogram of the Sample preparation corresponds to that of the Standard preparation as obtained in the Assay.
Container content	USP43-NF38	The average volume is less than 10% of that declared in the labelling, but the volume of no container is outside the range of 95% -110%
pH	USP43-NF38	3.0 to 6.0
Assay by HPLC.	USP43-NF38	90.0% to 120.0% of the stated amount.

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as illustrated in Table 27.

Table 29 Cephalexin suspension

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Deliverable volume	Assay
		County	Facility						
1.	NAI/CPH/26.06.2025/015	Nairobi City	Transwide Pharmaceuticals	Leocef	Laboratory & Allied Ltd	87906	Complies	98.5%	105.1%

4.5.3. Oral Contraceptives

4.5.3.1. Levonorgestrel 0.75mg Tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC.	BP 2024	In the test for Uniformity of Content, the retention time of the major peak of the Sample solution corresponds to that of Levonorgestrel Standard
Content Uniformity by HPLC	BP 2024	L1 Maximum acceptance value for 10 units- not more than 15
Assay by HPLC.	BP 2024	95.0% to 105.0% of the stated amount

Three samples failed to comply with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as illustrated in Table 28.

Table 30 Levonorgestrel tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Content Uniformity by HPLC
		County	Facility					
1.	NAI/LVG/26.06.2025/013	Nairobi	Transwide Pharmaceuticals-Nrb	Lydia Postpil 2	Montage Laboratories Pvt Ltd	ETM24036	Complies	Complies
2.	KSM/LVG/28.06.2025/038	Kisumu	Kentons Ltd	Ecee 2	Zydus Healthcare Limited	S400500	Complies	Complies
3.	KSM/LVG/26.06.2025/006	Kisumu	Handshake Chemist	Lydia Postpil 2	Montage Laboratories Pvt Ltd	ETM24036	Complies	Complies
4.	MRU/LVG/28.06.2025/017	Meru	Transwide Pharmaceuticals Ltd-Meru	Easyplan 2	Montage Laboratories Pvt Ltd	ETM24061	Complies	Complies

4.5.3.2. Levonorgestrel/Ethinylestradiol Tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC.	BP 2024	In the test for Uniformity of Content, the retention time of the major peak of the Sample solution corresponds to that of Levonorgestrel Standard
Content Uniformity by HPLC	BP 2024	L1 Maximum acceptance value for 10 units- not more than 15
Assay by HPLC.	BP 2024	95.0% to 105.0% of the stated amount

The sample complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia, as illustrated in Table 29.

Table 31 Levonorgestrel/Ethinylestradiol Tablets

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Assay
		County	Facility					
1.	KSI/LVG/26.06.2025/008	Kisii	Axar Pharmaceuticals Ltd	Femiplan	Mylan Laboratories Ltd	4002037	Complies	Levornogestrel: 98.8%. Ethinylestradiol: 92.9%
2.	NAI/LVG/26.06.2025/006	Nairobi	Transchem Pharmaceutical Limited	Femiplan	Mylan, Laboratories Ltd	8190854	Complies	Levornogestrel: 99.9%. Ethinylestradiol: 93.5%

5. DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1. Discussion

One hundred and forty (140) samples were collected from 60 facilities. These comprised both private (5) 8.33% facilities and public facilities (55) 91.66% spread across 22 of the 47 counties in Kenya.

As part of the field activity, facilities were audited for temperature and relative humidity monitoring in line with Good Storage Practices for HPTs. A total of 21 (36.67%) facilities monitored both temperatures and humidity, while 7 (11.67%) facilities did not monitor humidity but monitored temperature. A total of 31 (51.67%) facilities did not monitor the humidity and temperature of their storage areas. This is an area of concern that will require attention from both the national and County governments.

Product registration status was verified against the Pharmacy and Poisons Board (PPB) drug registration database. All one hundred and forty (140) product brands sampled were found to be registered and retained. All the 140 samples were subjected to level I screening and complied.

Of the 140 samples that underwent level I screening, one hundred and ten (110) underwent minilab screening (level II) whereby one hundred and nine samples complied while one (1) sample (Paradol suspension batch no. 240831) failed on appearance (crystals observed). Thirty samples did not have the minilab methods thus were excluded from minilab tests.

Forty-six (46) samples were subjected to compendial analysis. 42 complied with the specifications, and 4 samples failed to comply with the specifications.

For all non-compliant samples (both minilab and compendial), the table below summarizes the regulatory actions undertaken:

Table 32 Regulatory actions

Brand Name	INN	Batch No	Specification	Regulatory action
Paradol Suspension	Paracetamol	240831	Appearance (crystals observed)	Recall
Izzithree Suspension	Azithromycin	BPL 915A	Assay-84%	Recall

Cefuken DS	Cefuroxime	44B5411	Assay-87.6%	Recall
Zimycin Suspension	Azithromycin	ZIUO22404	Assay-80.7%	Recall
Medimol Suspension	Paracetamol	M13058	Assay-88.0%	Quarantined following an appeal for retesting by the MAH

5.2. Conclusion

In conclusion, the collection of 140 samples across 60 facilities in Kenya demonstrates a substantial effort toward monitoring and ensuring the quality of health products, achieving 68.6% of the targeted goal. Notably, antibiotics showed the highest collection success at 84.4%, while categories like analgesics and contraceptives presented significant challenges due to product availability. The data on storage of HPTs underscores the critical need for improved monitoring of temperature and relative humidity in storage facilities, as nearly 63.3% lacked adequate environmental controls. Additionally, geographical disparities highlight the need for tailored strategies to enhance access in remote areas. These insights will be invaluable for future surveillance planning, facilitating a more robust approach to address the operational challenges identified. The overall achievement not only reflects a commitment to quality assessment but also emphasizes areas requiring focused attention from both the National and County governments. Expedient regulatory action including quarantine and recall, was initiated concerning the products that failed to meet the established standards to ensure the protection and advancement of public health and safety.

5.3. Recommendations

1. In compliance with PPB's Good Storage Practices, responsible personnel in HPT storage premises should monitor and record both the temperature and relative humidity using calibrated equipment. Routine Good Distribution Practice (GDP) inspection activities should assess and enforce compliance with this requirement.
2. County Government support supervision activities should assess and ensure compliance with Good HPT storage requirements and guidelines.
3. The personnel in pharmacies and all HPT storage areas MUST consistently comply with the manufacturer's storage recommendations for ALL HPTs.
4. Prioritize counties/regions and HPT brands that missed out in the previous PMS activities for sampling in subsequent activities.

APPENDICES

Contributor	Institution
Dr. Ahmed Mohamed	PPB
Dr. Ali Arale	PPB
Dr. Christabel Khaemba	PPB
Dr. Edward Abwao	PPB
Dr. Lorna Wangari	PPB
Dr. Sichei Cheworei	PPB
Dr. Samuel Kerama	PPB
Dr. Pamela Nambwa	PPB
Dr. Onesmus Saidimu	PPB
Dr. Silas Gitonga	PPB
Dr. Ruth Njoga	PPB
Dr. Roselyne Mwihia	PPB
Mr. Too Maiyo	PPB
Dr. Vallarie Muguni	PPB
Dr. Clifford Omoke	PPB
Mr. Dalton Lemayian	PPB

ANNEXES

Annex 1: Sample Collection Form

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Unique Sample Code ______________________________

Transcribe the appropriate sample code in the following format: Region Initials / Molecule code/ Date samples were collected/ three-digit serial number)
e.g., NAI/GENT/05.05.2021/002

(The last 3 digits represent serialization of Samples with the first sample collected being 001, 2nd 002 etc.)

Origin of Sample

Facility Name:		Facility Code: **(Mandatory)**	

Product Details

Active Pharmaceutical Ingredient (API)/ INN			
Brand (Product name):			
Dosage Form: (E.g., tablets/, capsules, oral solution, *N/A* for medical devices)		Strength (e.g. 500 mg)	

Pack Size (e.g., 60s blister pack, 60ml bottle,100s loose)		No. of units per sample collected	
Name of Manufacturer: (e.g., Norvatis Pharma Ltd.)			
Manufacturer Address (Site of Manufacture): (e.g., Suffern, New York, USA)			
Batch or Lot #: (e.g., CF2012A4)		Date of Manufacture: (mmm/yyyy e.g., Mar/2015)	
Expiry Date: (mmm/yyyy e.g., Mar/2019)		Patient Information Leaflet Present? Yes/ No	
Manufacturer storage requirements (°C)			

Annex 2: Facility Details Form

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Pharmacy and Poisons Board	**Facility Details form**	**FOM037/HPT/PDS/VMS/SOP/011**
		Rev No. 0

Facility Code **(MANDATORY)**			
County:			
Name of Facility: (Use name in MFL list if applicable)			
Sector of Facility (Public, Private, Informal)			
Type of Facility (Hospital, Health Center)			
Contact Person: (Name of respondent at facility)			
E-mail address of contact Person:		Mobile number of	

		contact person:	
Date samples were collected at this facility (e.g., 10. 09. 2018)			
Where was the sample stored (Refrigerator, cabinet, shelf?)			
Did the fridge have fridge thermometer? YES NO			
What was the temperature recording?			
Did the storage area have a wall thermometer or thermohygrometer? YES NO			
Storage Temperature: (In area/ room where sample was picked e.g., 26.5° Celsius			
% Relative Humidity: (In area/ room where sample was picked e.g., 56.5%)			
Did the storage area have the temperature chart? YES NO			

Name & Signature of sample collectors:
1._____

2._____

Note:
Samples collected must remain in their original containers, intact and unopened.

This Sample Information Collection form should always be kept with the sample collected.
Proper sampling procedures should be followed.
The excel database should be properly filled
Faith-based** health care facilities shall be **categorized as private

Annex 3: Product Information Review Form

Unique sample code ____

Product name: _

INNs: _____

1- External packaging	**Information present on the label**
Product name	YES ☐ NO ☐
INN	YES ☐ NO ☐
Strength	YES ☐ NO ☐
Batch number	YES ☐ NO ☐
Manufacturing date	YES ☐ NO ☐
Expiry date	YES ☐ NO ☐
Manufacturer Name & Physical address	…… …… ……
Storage conditions	……
Labelling Language English / Kiswahili	YES ☐ NO ☐

2- Primary packaging	**Information present on the label**
Product name	YES ☐ NO ☐
Strength	YES ☐ NO ☐
Unit dose per blister or container stated	YES ☐ NO ☐
Batch number	YES ☐ NO ☐
Manufacturing date	YES ☐ NO ☐
Expiry date	YES ☐ NO ☐
Manufacturer name (Specify only if different from the external packaging under point 1)	YES ☐ NO ☐ ……

3- Package leaflet	
Presence of the leaflet	YES ☐ NO ☐
Language(s) of the leaflet	……
Composition	YES ☐ NO ☐

Manufacturer name & physical address (Specify only if different from the external packaging under point 1)	YES ☐ NO ☐ …… ……
Storage conditions (Specify only if different from the external packaging under point 1)	YES ☐ NO ☐ …… ……

Annex 4: Visual and physical inspection and MiniLab results form

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

TEST 1: VISUAL & PHYSICAL INSPECTION	
Visual Inspection:	
Please confirm that all of the recorded information in the Sample Collection Form (Annex 2) is consistent with the packaging and labeling of the medicine. Correct the Sample Collection Form (Annex 2) if there are any errors and/or omissions. Have any corrections and/or additions been made to Sample Collection Form (Annex 2): ☐ Yes ☐ No	
Other Comments (description of hologram, any print on the backing foil, etc.)	
Physical Inspection:	
Shape (circular, oval, flat sides, other)	
Uniformity of shape	
Uniformity of color	
No physical damage (cracks, breaks, erosion, abrasion, sticky)	
Other observations (no foreign contaminant, dirty marks, proper seal - for capsule)	

TEST 2: DISINTEGRATION[4]		
Time of observed disintegration (minutes) 1. _____ 2. _____ 3. _____	Did the drug pass the disintegration test? ☐ Yes ☐ No	
TEST 3: TLC		

Did the sample have a spot? ☐ Yes	Intensity of sample spot compared to standard:
☐ No Rf Standard: _____ Rf Sample: _____ Rf % Sample difference:[5] _____	○ Less than 80% ○ Between 80% and 100% ○ More than 100% Were there any contaminants/impurities present? ☐ Yes ☐ No Observations: _____
FINAL RESULTS	
○ The sample conformed with basic tests ○ The sample did not conform with basic tests Reason: _____ ○ The sample is considered doubtful Reason: _____	
How many units remain after basic tests? _____	
REPORT REVIEWED BY[6]:	
Name: _____ Signature: _____ Date: _____	

[5] Rf % Sample Difference = $\frac{|\text{Rf (Standard)-Rf (Sample)}|}{\text{Rf (standard)}} \times 100$

In this formula $|Rf\ (Standard) - Rf\ (Sample)|$ represents the absolute value of the difference between the
Rf's of the standard and the sample.
Ex: In a TLC run the following values are obtained: Rf (standard) = 0,55, Rf (sample) = 0,57;
The Rf % Sample
Difference = $\frac{|0.55-0.57|}{0.55} \times 100 = \frac{0.02}{0.55} \times 100 = 3.6\%$

[6] If applicable

Annex 5: Analysis request form

Pharmacy and Poisons Board	Analysis Request Form	*FOM003/QCL/SOP/002*
		Rev No: 4

Applicant Name		
Applicants Contact(s)		
Sample Name		
Sample Presentation		
Label Claim		
Manufacturer Name and Address		
Batch No.:	**Date of Manufacture:**	**Expiry Date:**
Storage Conditions		
Quantity Submitted		
Sample Source		
Nature of Complaint		
Class of HPT's	☐ Medical Product ☐ Medical Device ☐ Cosmetic ☐ Herbal Product ☐ Any Other	
Method of Analysis (tick appropriately)	☐ United States Pharmacopeia ☐ British Pharmacopeia ☐ International Pharmacopeia ☐ Manufacturers Method of Analysis ☐ Any Other Method	

Tests: ☐ Visual Inspection, ☐ Identification, ☐ Clarity of solution, ☐ Color Test, ☐ Uniformity of Weight, ☐ Deliverable Volume, ☐ Density, ☐ Particle Size distribution, ☐ Friability, ☐ Disintegration, ☐ Optical Rotation, ☐ pH, ☐ Dissolution, ☐ Weight Variation, ☐ Uniformity of Content, ☐ Assay, ☐ Microbial Identification, ☐ contamination test, ☐ Microbial Load and ☐ Sterility, ☐ Preservative Efficacy Test, ☐ Bacterial Endotoxin Test, ☐ Microbial Assay, ☐ Challenge Test, ☐ Penetration Test, ☐ Leak Test, ☐ Plunger force, ☐ Burst Volume, ☐ Tensile Strength, ☐ Lubricant Test, ☐ Dimensions, ☐ Sensitivity, ☐ Selectivity.

Pharmacy and Poisons Board	Analysis Request Form	*FOM003/QCL/SOP/002*
		Rev No: 4

Applicant Signature: **Date:**

<u>For Laboratory Use Only</u>

QC Reference No.:

	Name	Date	Sign
Received By			
Authorized By			

The Pharmacy and Poisons Board

P. O. Box 27663- 00506 Lenana Road Opposite Russian Embassy Nairobi,

Tel: +254-02 – 12345/ 6789, Fax: +254-02- 12345

Website**:** www.pharmacyboardkenya.org.ke,

Email: info@pharmacyboardkenya.org.ke