
**MINISTRY OF HEALTH**

**PHARMACY AND POISONS BOARD**

# REPORT ON RISK-BASED POST-MARKETING SURVEILLANCE AND EXTENDED INVESTIGATION OF SELECTED HEALTH PRODUCTS AND TECHNOLOGIES IN THE KENYAN MARKET

**MARCH 2026**

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## EXECUTIVE SUMMARY

The Pharmacy and Poisons Board (PPB) conducted a targeted, risk-based post-marketing surveillance (PMS) exercise between October 2025 and March 2026. The investigation focused on product batches previously suspected or confirmed to be substandard, using distribution data provided by Marketing Authorization Holders (MAHs) and Local Technical Representatives (LTRs) to verify the extent and geographic spread of reported quality defects.

Unlike routine PMS surveys which rely on random or representative sampling to estimate the general market prevalence of substandard or falsified products, this exercise was intelligence-led and purposive. Products and batches were deliberately selected based on prior evidence of quality concerns, including out-of-specification (OOS) laboratory results, product quality complaints, and Chemistry, Manufacturing and Controls (CMC) deficiencies identified during Good Manufacturing Practice (GMP) inspections.

A key objective was to determine whether previously identified OOS findings stemmed from intrinsic manufacturing or product quality defects within the supply chain, or whether they could be attributed to isolated factors such as sample handling, storage, transportation, or laboratory processes.

Of the 112 samples tested, 94 complied with established quality specifications. However, because the exercise was designed to confirm the presence, extent, and distribution of high-risk products, not to estimate national prevalence, these results should not be interpreted as a general market failure rate. The targeted methodology inherently carried a higher probability of detecting non-compliance.

Appropriate regulatory actions have been instituted for all non-complying products and batches identified during the investigation.

Dr Ahmed I. Mohamed
**Chief Executive Officer**

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## ACRONYMS & ABBREVIATIONS

| | |
|---|---|
| **API** | Active Pharmaceutical Ingredient |
| **GDP** | Good Distribution Practices |
| **GMP** | Good manufacturing Practices |
| **HPTs** | Health Products and Technologies |
| **LMICs** | Low- and Middle-Income Countries |
| **OOS** | Out of Specification |
| **PPB** | Pharmacy and Poisons Board |
| **PMS** | Post Marketing Surveillance |
| **QC** | Quality Control |
| **SF** | Substandard and falsified |
| **TLC** | Thin layer chromatography |
| **WHO** | World Health Organization |

## DEFINITION OF TERMS

| | |
|---|---|
| **Falsified Health products** | A product that is deliberately and fraudulently Mislabeled with respect to identity and / or source". |
| **Extended Investigation** | Structured regulatory and technical activities conducted following confirmation of a quality defect e.g., OOS result, or other non-compliance) to determine the full scope, root cause, and potential public health impact of the defect beyond the initially affected sample or batch. The investigations assess whether the defect is confined to a single batch or extends to other related batches, other products manufactured under similar conditions, or specific manufacturing, storage, or distribution locations, to guide appropriate regulatory action. |
| **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) |
| **Active PMS** | Coordinated surveys, sampling and analysis, evaluation and assessment of regulatory requirements in relation to labelling, storage etc. |
| **Reactive PMS** | 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. |

**ACKNOWLEDGEMENT**

The Pharmacy and Poisons Board acknowledges the dedicated efforts of the PPB teams, as well as the participating health facilities and manufacturers, for their cooperation during this surveillance exercise.

# 1.0 INTRODUCTION

## 1.1 Background

Substandard and falsified (SF) health products and technologies (HPTs) pose a significant threat to public health, particularly in low- and middle-income countries (LMICs), where the World Health Organization (WHO) estimates that 10% of HPTs circulating are either substandard or falsified (SF)[1]. SF HPTs contribute to treatment failure, adverse reactions, increased morbidity and mortality, antimicrobial resistance (AMR), and wasted healthcare resources and costs[2]. Vulnerable populations are disproportionately affected.

Within the East African Community (EAC), studies have documented persistent quality challenges. A regional study across Ethiopia, Kenya, Rwanda, and Tanzania identified SF products in 151 of 669 antimicrobial samples[3].

The Pharmacy and Poisons Board (PPB) conducted post-market surveillance (PMS) on antimalarials and maternal and child health products from 2022 to May 2024, reporting a 99.25%[4]. This high pass rate likely reflects sampling of lower-risk products, contrasting with persistent market complaints that have necessitated regulatory actions such as recalls and quarantines[5]. This divergence underscores the need for a complementary, risk-based surveillance strategy targeting higher-risk products and manufacturers.

[1] World Health Organization (W.H.O) (n.d). 1 in 10 medical products in developing countries is substandard or falsified. Retrieved from https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified

[2] 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.

[3] Tegegne, A. A., Feissa, A. B., Godena, G. H., Tefera, Y., Hassen, H. K., Ozalp, Y., & Suleman, S. (2024). Substandard and falsified antimicrobials in selected east African countries: A systematic review. PLoS One, 19(1), e0295956.

[4] https://web.pharmacyboardkenya.org/recalls-and-withdrawals/

[5] https://web.pharmacyboardkenya.org/recalls-and-withdrawals/

### 1.2 Problem Statement and Justification

The presence of SF HPTs in the Kenyan market undermines public health and trust in the healthcare system. The PPB has received multiple quality complaints regarding selected HPTs manufactured locally and in countries such as China, India, and Bangladesh. Internal data (2023–2025) indicate that market complaints were predominantly associated with locally manufactured products (44.4%), followed by imports from India (35.8%), China (4.3%), and Bangladesh (3.9%)[6].

This risk-based PMS study is therefore critical to verifying the quality and regulatory compliance of selected HPTs, detecting SF products, generating actionable data for regulatory action, and establishing a framework for extended investigations to guide proportionate and effective responses to quality defects.

This report presents the findings of that risk-based survey, and the extended investigations conducted following confirmation of quality defects.

[6] PPB Analysis of reported suspected poor-quality reports

## 2.0 OBJECTIVES

### 2.1 General objective

To strengthen the safety and quality assurance of Health Products and Technologies (HPTs) in the Kenyan market through risk-based post-marketing surveillance and extended investigations following confirmation of quality defects.

### 2.2 Specific objectives

a. To conduct extended investigations following confirmation of quality defects to determine root cause and thereby guide appropriate regulatory action.

b. To verify the quality and regulatory compliance of selected HPTs circulating in the Kenyan market by assessing their conformance to market authorization requirements.

c. To generate data that will inform risk-based decision-making, including regulatory inspections, enforcement, and future surveillance planning.

## 3.0 METHODOLOGY

### 3.1 Surveillance Scope and Design

This follow-up survey was designed as an extended investigation targeting previously identified non-compliant products and manufacturing facilities. A risk-based approach was used to prioritize high-risk brands and batches for sampling.

The survey was conducted between 30th October 2025 and 3rd November 2025 (sampling phase), with laboratory analysis completed by March 2026.

### 3.2 Selection of Products, Batches, and Regions

Three risk-based inputs guided product selection for the survey:

a. Non-Complying Products List: Products with prior laboratory failures or non-compliance (2024/2025 PMS).
b. Manufacturer Risk History List: Products from manufacturers classified as high-risk or with GMP non-compliance.
c. Product Quality Complaints List: Products frequently linked to market complaints, adverse drug reactions or recalls.

Batch Selection: Four batches per selected product brand were targeted, prioritized as:

a. Complaint batches linked to prior quality complaints.
b. Campaign-manufactured batches with wide-scale distribution.
c. Batches with linked quality concerns from the same manufacturer.
d. One batch per facility to ensure broad geographic representation.

Each product was identified by brand name and manufacturer to ensure traceability.

Regions: Sampling occurred in 11 counties selected based on the distribution list of the selected products and their specific batches, climatic stress factors (high humidity/temperature), historical risk data, and prior identification of falsified products: Kakamega, Kiambu, Kisii, Kisumu, Machakos, Mombasa, Murang'a, Nairobi, Nakuru, Nyeri and Uasin Gishu

### 3.3 Sample Size, Facility Selection, and Substitution

The target sample size was 128 samples (4 batches × 32 selected product brands). A total of 112 samples were ultimately collected.

Facilities prioritized included those that had previously submitted complaints, key wholesalers, distributors, retailers, logistical companies, local manufacturers, healthcare facilities, and central procurement stores (KEMSA, MEDS). Samples were collected from both public, private, and faith-based healthcare facilities.

**Substitution criteria:** If the primary target batch was unavailable, collectors followed a hierarchical approach:

1. Different batch, same brand and manufacturer.
2. Same API and dosage form from a different high-risk manufacturer.
3. Contacted central coordination for guidance if no risk-based product was available.

All substitutions were documented on the sample collection form.

A centrally coordinated sampling strategy ensured national consistency. A total of four batches per product brand were collected. Where targeted samples were unavailable, documented substitution criteria was applied.

### 3.4 Sample Size, Facility Selection, and Substitution

The sample size for the survey was 128 samples *(4 batches × 32 selected product brands)* were to be collected. Central real-time monitoring was employed to prevent duplication.

For facility selection, priority was given to facilities that previously submitted complaints, including key wholesalers, distributors, retailers, high-risk manufacturers, healthcare facilities, and central procurement stores.

**Substitution Criteria:** If the primary target (complaint batch) was unavailable, collectors followed a hierarchical approach of:

1. Different batch, same brand and manufacturer.
2. Same API and dosage form from a different high-risk manufacturer.
3. Contacted central coordination for guidance if no risk-based product is available.

### 3.5 Sample Definition and Handling

A sample was defined by: product name, active ingredient, manufacturer, dosage form, strength, batch/lot number, collection site, and packaging material.

The number of sample units collected followed Table 1 and was to be sufficient for screening, compendial testing, investigation of OOS results, and retention for dispute resolution.

#### 3.5.1 Sample Sizes per Dosage Form

Table 1Sample size per dosage form

| Dosage Form | Sample Size |
|---|---|
| Tablets/Capsules | 100 Units |
| Suspensions/Syrups (<20 Ml) | 40 Bottles |
| Suspensions/Syrups (20–100 Ml) | 20 Bottles |
| Suspensions/Syrups (100–500 Ml) | 10 Bottles |
| Suspensions/Syrups (>500 Ml–5l) | 3 Bottles |
| Injections (Vials, <10 Ml) | 100 Vials |
| Injections (Vials, 10–100 Ml) | 50 Vials |
| Injections (Vials, >100 Ml) | 10 Bottles |

| Dosage Form | Sample Size |
|---|---|
| Injections (Ampoules, <10 Ml) | 100 Ampoules |
| Injections (Ampoules, 10–100 Ml) | 50 Ampoules |

Each sample was assigned a unique code (County/Product/Date/Sequential Number). Thermohygrometer data loggers monitored storage and transport conditions. All original packaging and leaflets were retained.

### 3.5.2 Sample Handling

1. Each sample was labelled with a unique code: County Code/Product Code/Date/Sequential Number,
2. Recorded expiry date (samples near expiry could only be collected but documented the reason for collection),
3. Maintained all original packaging and leaflets,
4. Thermohygrometer data loggers were used to monitor storage and transport conditions,
5. Samples were shipped to PPB main office under appropriate storage conditions.

### 3.5.3 Field Work Preparation

A designated team of sample and data collectors conducted sampling across all selected regions. A one-day training workshop was held prior to fieldwork, covering:

a. Use of data and sample collection tools,
b. Sampling techniques and the hierarchical substitution protocol,
c. Sample handling, storage, and transport requirements,
d. Data entry and management procedures.

### 3.5.4 Sample Collection Procedures

At each sampling site, the collection team performed the following functions:

**a. Obtained Records**

- Collected temperature and humidity monitoring records from the facility, where available.
- Documented any observations regarding storage conditions or handling practices.

**b. Collected Samples**

- Collected samples in their original, unopened packaging.
- Ensured all package inserts and accompanying materials were retained.
- Recorded the expiry date; Where possible, collected samples with sufficient remaining shelf life to allow for complete testing. However, samples with less than six (6) months to expiry could only be collected if they were the primary target (e.g., complaint batches) or if no alternative exists. The expiry date was recorded, and results would be interpreted in context.

**c. Label Samples**

Assigned a unique sample code to each sample container using the format:

County Code / Product Code / Date / Sequential Number

Example: NBI / GEM / 27.08.2026 / 005

Table 2 Samples labelling guide

| Component | Description |
|---|---|
| A: County Code | Three-letter code as per gazette notice (e.g., NBI for Nairobi) |
| B: Product Code | Abbreviation for active ingredient and dosage form, as per Table 4 |
| Date | Date of sample collection (DD.MM.YYYY) |
| Sequential Number | Three-digit number unique to the sample (e.g., 005) |

|**C: Date** | Date of sample collection (DD.MM.YYYY) |
|**D: Sequential Number** | Three-digit sequential number unique to the sample (e.g., 005) |

Table 3 Product Code Key

| Dosage Form | Code Suffix |
|---|---|
| **T** | Tablet |
| **C** | Capsule |
| **I** | Injection |
| **S** | Suspension/Solution/Syrup |

*Example: Amoxicillin Tablets = AMX-T; Metronidazole Suspension = MET-S*

Labelling was completed immediately at the time of sampling to prevent mix-ups. A master sample log was maintained linking each unique code to all raw data.

Product code (e.g. ART for Gemcitabine Injection) as indicated in table 4 below,

Table 4: Product code

| S/No | API | Code |
|---|---|---|
| 1. | Amoxicillin | AMX-C/T/S |
| 2. | Amitriptyline | AMIT |
| 3. | Chlorpromazine | CTZT |
| 4. | Ampicillin/Cloxacillin | AMCC/S |
| 5. | Albendazole | ALBS |
| 6. | Azithromycin | AZTS |
| 7. | Ferrous and folic acid | FSFT |
| 8. | Cephalexin | CEPS |
| 9. | Ciprofloxacin | CPFT |
| 10. | Dextrose | GLUI |
| 11. | Flucloxacillin | FLXC/S |
| 12. | Ibuprofen/ Paracetamol | IBUS |
| 13. | Hydrochlorothiazide | HCTT |
| 14. | Methyldopa | MEDT |
| 15. | Metronidazole | METT/S |
| 16. | Paracetamol | PCTT/S |
| 17. | Tetracycline | TETO |
| 18. | Rivaroxaban | RVIT |
| 19. | Daflon | DHET |

**d. Completed Documentation**

- Recorded all sample information in the Sample Collection Form, Facility Details Form, and Product Information Review Form.

- Entered data into the Excel Aggregation Tool for central monitoring.
- Where required information was unavailable, indicated "not available" in the appropriate space.
- Recorded any relevant observations (e.g., damaged packaging, questionable storage conditions) in the spaces provided.

**e. Package and Store**

- Packed each sample with its completed collection form in the provided packaging materials (Ziploc bags, cartons) and sealed appropriately.
- Stored samples in accordance with the manufacturer's storage instructions (e.g., temperature, light protection).
- Deployed thermohygrometer data loggers with each shipment to monitor transport conditions.

**f. Shipped Samples**

- Shipped samples to the PPB main office using appropriate transport modes (land or air) depending on accessibility.
- Ensured adherence to manufacturer's storage recommendations throughout transit.
- Took adequate measures to prevent physical or chemical damage to samples.

**g. Submitted Field Summary Report**

- Prepared and submitted field summary report using the format in Annex 6, documenting:
    - Number of samples collected,
    - Any deviations from the sampling plan,
    - Challenges encountered,
    - Notable observations at facilities.

### 3.6 Laboratory Analysis

All samples were first verified for registration status with the PPB. Only authorized products underwent laboratory analysis.

**Level I – Visual/Physical Inspection:** All 112 samples were examined at the PPB QC laboratory for visual quality defects, packaging integrity, and presence of patient information leaflets.

**Level II – Minilab® Screening:** A total of 111 samples (screening was not performed on 7 samples due to lack of a validated Minilab® method for the specific API/dosage form) underwent Thin Layer Chromatography (TLC) and disintegration testing where applicable at the PPB QC laboratory. The test results for each sample tested was recorded on the Visual/physical inspection, and the Minilab® results form Annex 5: Visual and physical inspection and Minilab® results form

Once testing was finalized, all tested samples with their respective forms and TLC plates attached were filled and archived at the PPB QC laboratory.

**Level III – Confirmatory Compendial Testing:** A total of 112 samples were subjected to full compendial analysis Testing followed British Pharmacopoeia (BP), United States Pharmacopoeia (USP), or International Pharmacopoeia methods. Parameters included identity, assay, dissolution, friability, disintegration, pH, and sterility as appropriate. The analysis were conducted in PPB QC laboratory and other PPB-prequalified quality control laboratory.

**Criteria for Level III testing:**

- All samples that failed Level I or II.
- All samples with doubtful results at Level II.
- 20% of each brand that passed Level II (random selection).
- All samples lacking a Minilab® screening protocol.

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 PPB laboratory, joint re-testing with the LTR/manufacturer representative were carried out at the PPB QCL or retest at PPB-prequalified lab at the LTR/manufacturer cost.

A Certificate of Analysis (COA) or Laboratory analysis report (LAR) that entails a summary of the results obtained were issued for each sample analyzed.

For substituted products the test parameters conducted were based on the dosage form as per Table *7*

Test parameters conducted on the sampled products are as shown in Table *6*

**Table 5: Sample test parameters**

| S/N | Brand | Inn | Formulation | Test Parameters |
|---|---|---|---|---|
| 1. | Amitrip | Amitrityline | Tablet | ID, Assay, Dissolution, Friability, Disintegration |
| 2. | Alimox | Amoxicillin | Oral Suspension | ID, Assay |
| 3. | Cloxam | Ampicillin/Cloxacillin | Oral Suspension | ID, Assay |
| 4. | Zerocin | Azithromycin | Oral Suspension / Syrup | ID, Assay |
| 5. | ZIMYCIN | Azithromycin | Oral Suspension | ID, Assay |
| 6. | Cefuken DS Syr | Cefuroxime | Oral Suspension | ID, Assay |
| 7. | Exime DS | Cefuroxime | Oral Suspension / Syrup | ID, Assay |
| 8. | Leocef | Cephalexin | Injection | ID, Assay, pH |
| 9. | Ciprolab | Ciprofloxacin | Oral Tablets / Capsules | ID, Assay, Dissolution, Friability, Disintegration |
| 10. | Lecotrim | Cotrimoxazole | Oral Suspension | ID, Assay |
| 11. | Dexatas | Dextroese | Injection | Assay |
| 12. | IFAS | Ferrous Sulphate; Folic Acid | Tablet | ID, Assay, Dissolution, Friability, Disintegration |
| 13. | Dawa-Flox Tablets | Flucloxacillin | Oral Tablets / Capsules | ID, Assay, Dissolution, Friability, Disintegration |
| 14. | Medopress | Methyldopa | Tablet | ID, Assay, Dissolution, Friability, Disintegration |
| 15. | Daflon | Micronized Flavanoid | Tablets | ID, Assay |
| 16. | Medimol | Paracetamol | Oral Suspension | ID, Assay |
| 17. | Paratal | Paracetamol | Tablet | ID, Assay, Dissolution, Friability, Disintegration |
| 18. | Ibuflam plus | Paracetamol/Ibuprofen | Oral Suspension | ID, Assay |
| 19. | Phenytoin | Phenytoin | Tablet | ID, Assay, Dissolution, Friability, Disintegration |
| 20. | Hartezee | Rivaroxaban | Tablet | ID, Assay, Dissolution, Friability, Disintegration |
| 21. | Racycline | Tetracyline | Eye ointment | Sterility |

**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 |

## 3.7 Data Analysis, Interpretation, and Dissemination

### 3.7.1 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 application of standardized tools for data and samples collection. The teams carrying out data and sample collection was supervised by a central coordination team. Screening and compendial testing of the samples were undertaken using the laboratory SOPs and guidelines.

### 3.7.2 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 substandard or falsified. The WHO’s definition was used to classify the HPTs as “Substandard or falsified”.

### 3.7.3 Regulatory Actions

The necessary and appropriate regulatory actions were taken for products that did not meet the marketing authorisation requirements of the country.

# 4.0 Results

## 4.1 Samples collected

One hundred and twelve samples composed of different active pharmaceutical ingredients (API) were collected as indicated below in Figure 1 Distribution of samples collected. Paracetamol was the highest collected API at 14 samples followed by rivaroxaban with 12. The least collected APIs were Albendazole, APC, 5% glucose, flucloxacillin and Ampicillin/cloxacillin at one each.

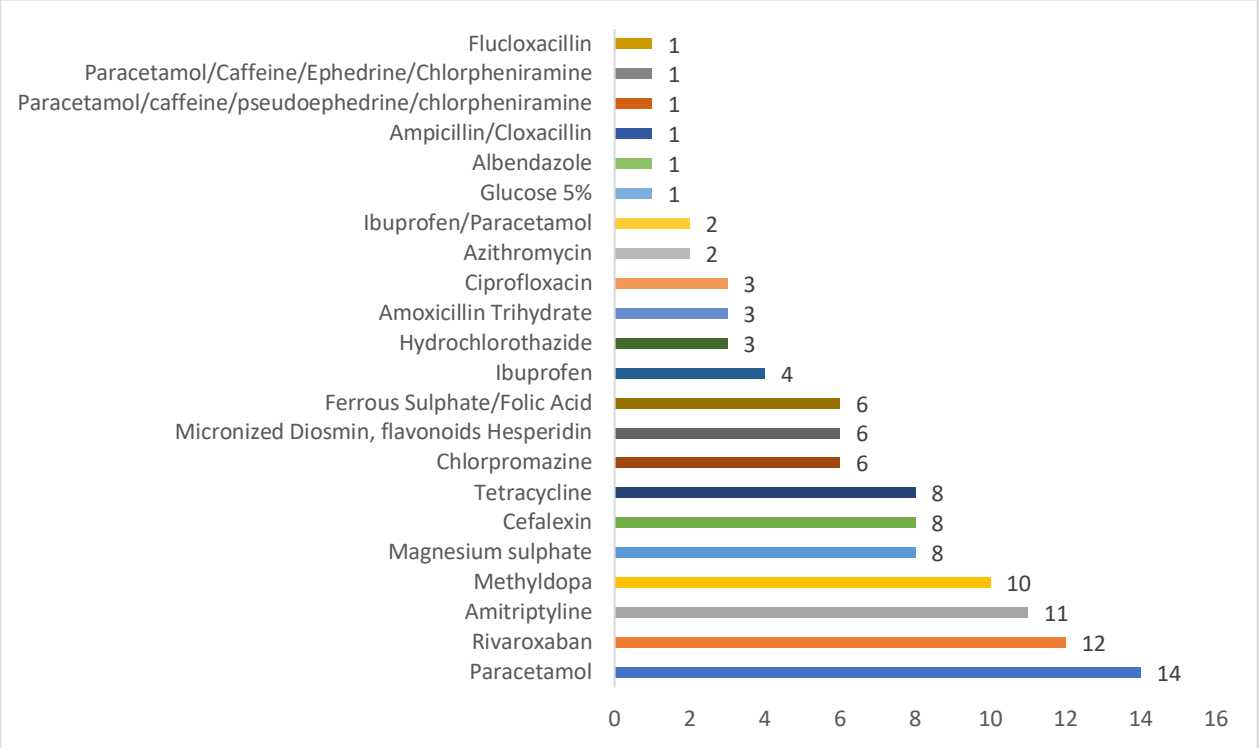


Figure 1 Distribution of samples collected

The 112 samples were collected from 38 facilities. These comprised private facilities (78) 66.10%, public facilities (31) 26.27% and Faith based organization (3) 2.54% spread across 11 of the 47 counties in Kenya, see Figure 2 Sample distribution by counties.

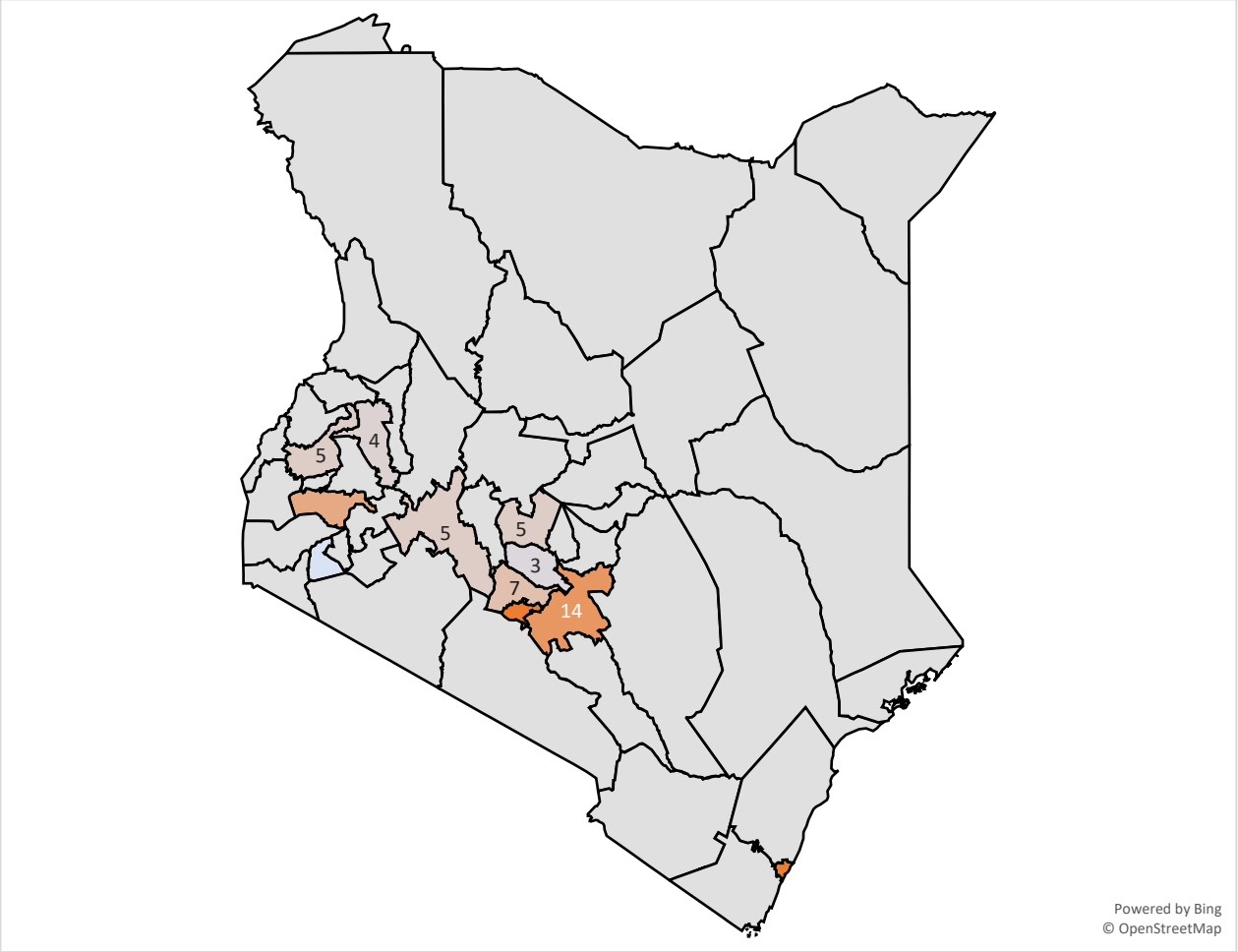


Figure 2 Sample distribution by counties

In terms of facility type, the products were sampled from Central Procurement Agencies, County Referral hospitals, Manufacturers, National Referral Hospital, Private Distributor, Private Pharmacy and Sub County Hospitals. See Figure 3 Samples collected by facility type

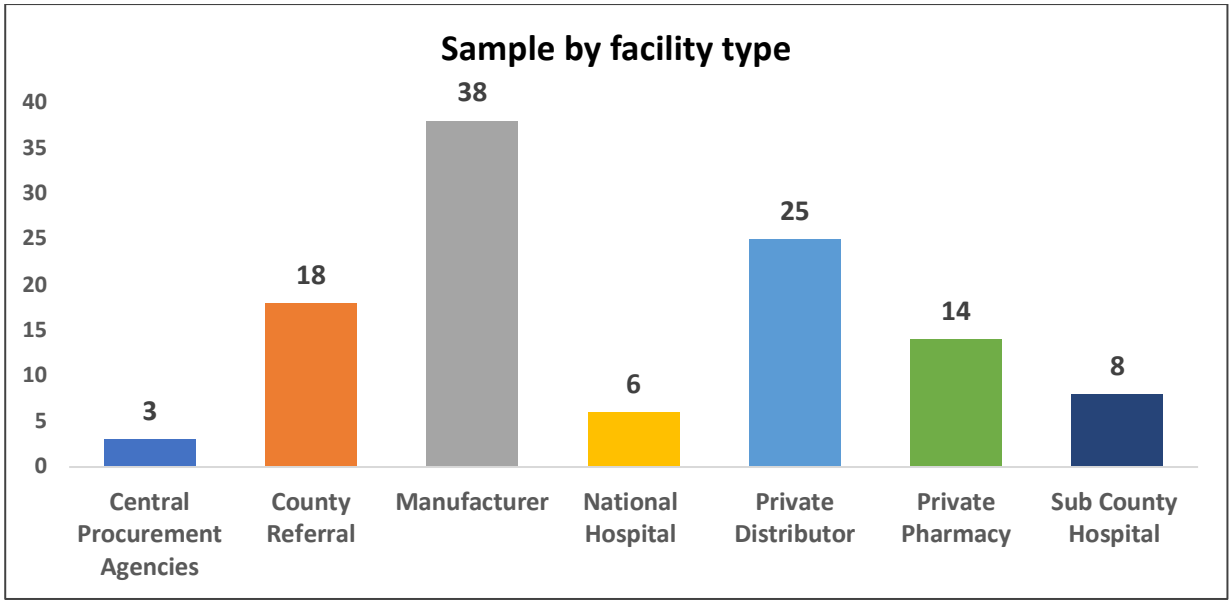


Figure 3 Samples collected by facility type

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 versus the actual samples collected*

| API/Product Category | Target samples (No. of Batches) | Actual Samples Collected | Achievement Rate | Variance |
|---|---|---|---|---|
| Albendazole | 4 (4 batches × 1 brand) | 1 | 25% | -3 |
| Amitriptyline | 4 (4 batches × 1 brand) | 11 | 275% | +7 |
| Amoxycillin | 4 (4 batches × 1 brand) | 3 | 75% | -1 |
| Ampicillin/Cloxacillin | 4 (4 batches × 1 brand) | 1 | 25% | -3 |
| Azithromycin | 8 (4 batches × 2brands) | 2 | 25% | -6 |
| Cephalexin | 4 (4 batches × 1 brand) | 8 | 200% | +4 |
| Chlorpromazine | 4 (4 batches × 1 brand) | 6 | 150% | +2 |
| Ciprofloxacin | 4(4 batches × 1 brand) | 3 | 75% | -1 |
| Ferrous sulphate + Folic acid | 4 (4 batches × 1 brand) | 6 | 150% | +2 |
| Flucloxacillin | 4 (4 batches × 1 brand) | 1 | 50% | -2 |
| Glucose 5% | 4 (4 batches × 1 brand) | 1 | 25% | -3 |
| Hydrochlorothiazide | 4 (4 batches × 1 brand) | 3 | 75% | -1 |
| Ibuprofen | 4 (4 batches × 1 brand) | 4 | 100% | 0 |
| Ibuprofen/Paracetamol | 4 (4 batches × 1 brand) | 2 | 50% | -2 |
| Magnesium sulphate | 4 (4 batches × 1 brand) | 8 | 200% | +4 |
| Methyldopa | 4 (4 batches × 1 brand) | 10 | 250% | +6 |
| Micronized flavonoid | 4 (4 batches × 1 brand) | 6 | 150% | +2 |
| Paracetamol | 8 (4batches × 2 brands) | 14 | 175% | +6 |

| API/Product Category | Target samples (No. of Batches) | Actual Samples Collected | Achievement Rate | Variance |
|---|---|---|---|---|
| Paracetamol/Caffeine/Ephedrine/Chlorpheniramine | 4 (4 batches × 1 brand) | 1 | 25% | -3 |
| Paracetamol/caffeine/pseudoephedrine/chlorpheniramine | 4 (4 batches × 1 brand) | 1 | 25% | -3 |
| Rivaroxaban | 4 (4 batches × 1 brand) | 12 | 300% | +8 |
| Tetracycline | 4 (4 batches × 1 brand) | 8 | 200% | +4 |
| **Total** | **128** | **112** | **87.50%** | **-16** |

### 4.2 Storage conditions

Environmental conditions monitoring of temperature was being done in 37 out of the 38 facilities. The mean temperature for the facilities was 24.72$^0$c (range: 19.8$^0$c - 29.5$^0$c) with the minimum temperature at the JOOTRH site and the highest temperature in Tudor Mombasa. Thirty out of the 37 facilities were monitoring humidity. The average humidity for the facilities was 58% (range: 23% - 73%). All samples were transported and stored within manufacturer-recommended conditions per data logger records.

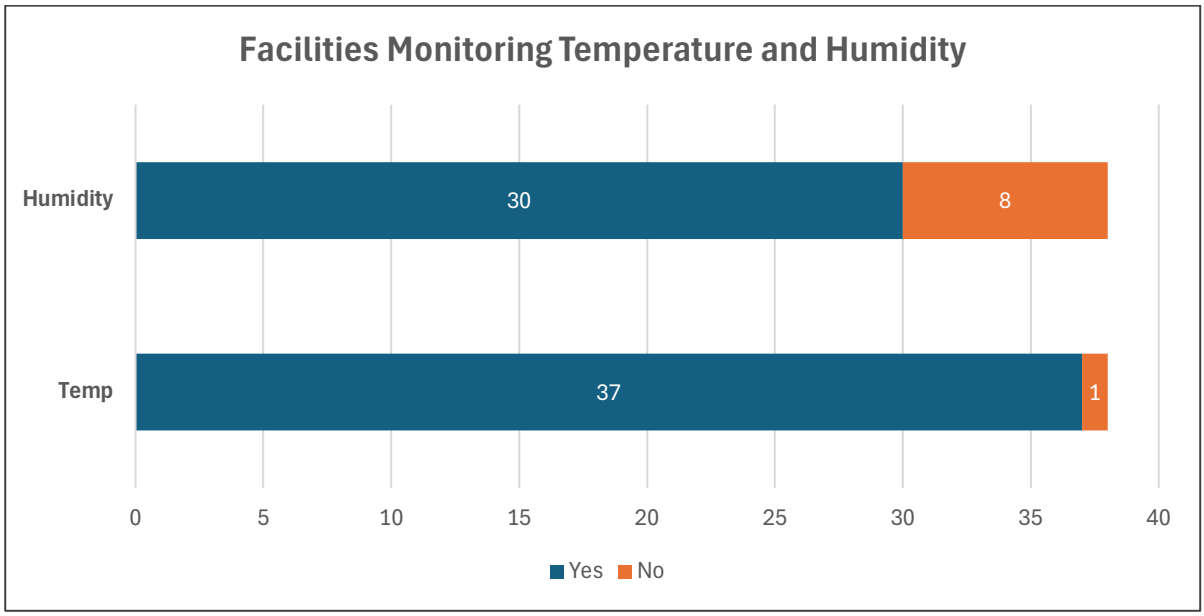


Figure 4 Environmental condition monitoring

### 4.3 Registration Status

All the collected 112 samples were checked for PPB's registration status. All the samples were found to be duly registered and retained.

### 4.4 Testing Results

A total of 112 samples underwent confirmatory testing.

**Overall confirmatory pass rate:** 83.92% (94 of 112 tested samples). Eighteen samples failed confirmatory testing.

*Table 8 Confirmatory testing results*

| API/Product Category | Samples Tested | Samples Complied | Samples Failed | Non-compliant Products |
|---|---|---|---|---|
| Albendazole | 1 | 0 | 1 | Zolas Suspension Batch 250407 |
| Amitriptyline | 11 | 11 | 0 | |
| Amoxycillin | 3 | 3 | 0 | |
| Ampicillin/Cloxacillin | 1 | 1 | 0 | |
| Azithromycin | 2 | 2 | 0 | |
| Cephalexin | 8 | 6 | 2 | Leocef DPS Suspension Batch 88579 |
| Chlorpromazine | 6 | 4 | 2 | Chlorpromazine Tablets Batch 83863, 83315 |
| Ciprofloxacin | 3 | 0 | 3 | Ciprolab Tablets Batch 84660, 84659, 84225 |
| Ferrous sulphate + Folic acid | 6 | 6 | 0 | |
| Flucloxacillin | 1 | 1 | 0 | |
| Glucose 5% | 1 | 1 | 0 | |
| Hydrochlorothiazide | 3 | 3 | 0 | |
| Ibuprofen | 4 | 4 | 0 | |
| Ibuprofen/Paracetamol | 2 | 2 | 0 | |
| Magnesium sulphate | 8 | 0 | 8 | Magnesium Sulphate Batch 89183, 89182, 89181, 88690, 88688, 88683, 86718, 85055 |
| Methyldopa | 10 | 9 | 1 | Medopress Batch 221138 |
| Micronized flavonoid | 6 | 6 | | |
| Paracetamol | 14 | 13 | 1 | Paratal Batch 83730 |
| Paracetamol/caffeine/pseudoephedrine/chlorpheniramine | 2 | 2 | 0 | |
| Rivaroxaban | 12 | 12 | 0 | |
| Tetracycline | 8 | 8 | 0 | |
| **Total** | **112** | **94** | **18** | |

**Note:** Eighteen samples were non-compliant, representing multiple batches of seven distinct products. Some products (e.g., Magnesium Sulphate) had multiple batches that all failed, indicating a systemic issue.

Regulatory actions were taken for the non-compliant products as seen in Table 9

### 4.5 PMS Regulatory Actions

Table 9 Summary of regulatory actions taken for noncompliant samples

| S. No. | Brand Name | API | Strength | Formulation | Manufacturer | Batch Number | Test Result | Regulatory Action |
|---|---|---|---|---|---|---|---|---|
| 1. | Chlorpromazine | Chlorpromazine | 100mg | Tablets | Laboratory & Allied Ltd | 83315<br>83863 | Does Not Comply | Recalled |
| 2. | Ciprolab | Ciprofloxacin | 500 mg | Tablets | Laboratory & Allied Ltd | 84225<br>84659<br>84660 | Does Not Comply | Recalled |
| 3. | Leocef DPS | Cefalexin | 125mg/5mL | Suspension | Laboratory & Allied Ltd | 88579 | Does Not Comply | Recalled |
| 4. | Magnesium Sulphate | Magnesium sulphate | Queried | Injection | Laboratory & Allied Ltd | 85055, 86718<br>88683, 88688<br>88690, 89181<br>89182, 89183 | Does Not Comply | Recalled |
| 5. | Medopress | Methyldopa | 250 mg | Tablets | Cosmos Pharmaceuticals Ltd | 221138 | Does Not Comply | Recalled |
| 6. | Paratal | Paracetamol | 500 mg | Tablets | Laboratory & Allied Ltd | 83730 | Does Not Comply | Recalled |
| 7. | Zolas | Albendazole | 200 mg /5mls | Suspension | Dinlas Pharma (Africa) Ltd | 250407 | Does Not Comply | Recalled |

The recalls can be found at PPB Recalls

In addition to the recall of the above non-compliant products, the manufacturing facilities underwent a For Cause GMP inspection to get the root cause of the product failures.

Facilities that did not comply with the prescribed environmental monitoring requirements were issued with formal regulatory observations and required to implement corrective actions. These included procurement, installation, and routine calibration of appropriate temperature and relative-humidity monitoring devices; establishment and implementation of documented environmental monitoring, review, and excursion-management procedures; designation of responsible personnel; maintenance of monitoring records; and provision of appropriate staff training. Compliance with the corrective actions was to be verified through regulatory follow-up within a specified timeframe.

## 5.0 Discussions

Unlike routine PMS surveys which rely on random or representative sampling to estimate the general market prevalence of substandard or falsified products, this exercise was intelligence-led and purposive. Products and batches were deliberately selected based on prior evidence of quality concerns, including out-of-specification (OOS) laboratory results, product quality complaints, and Chemistry, Manufacturing and Controls (CMC) deficiencies identified during Good Manufacturing Practice (GMP) inspections.

This expanded surveillance had a compliance rate of 83.92% (94 of 112 tested samples) among high-risk products passed analysis.

However, these findings should be interpreted within the context of the study design, as the survey intentionally targeted manufacturers and products identified as higher risk based on historical quality complaints, GMP inspection findings, and PMS intelligence. Consequently, the results are not representative of the overall quality of locally manufactured products and should not be interpreted as an indication of the performance of the local pharmaceutical manufacturing sector as a whole.

### 5.1 Limitations

1. Sampling frame: Only 11 of 47 counties were sampled due to focus on the distribution list of where the batches were distributed. Findings may not be generalizable to the entire country.
2. Over-sampling of specific manufacturers: The high proportion of Laboratory & Allied Ltd products in the sample (by design) means failure rates cannot be extrapolated to the wider market.
3. Substitution bias: When target batches were unavailable (e.g., Ampicillin/Cloxacillin only 1 of 4 targets collected), substitutes may not have equivalent risk profiles.

# 6.0 CONCLUSION AND RECOMMENDATIONS

## 6.1 Conclusion

This risk-based PMS extended investigation survey, successfully identified substandard products among targeted high-risk HPTs, confirming the need for the expanded investigations following OOS results. The majority of failures were among locally manufactured products from a small number of manufacturers with prior GMP deficiencies or complaint history. Regulatory actions including recalls and 'For Cause' GMP inspections have been implemented, and corrective action plans are under review. No falsified products were identified in the survey.

## 6.2 Recommendations

1. Permanently adopt a risk-based sampling strategy for routine PMS, allocating more sampling resources to high-risk products (prior OOS, complaint history, high-risk manufacturers) and less to random surveillance for market baseline.
2. Implement regular screening of HPTs though Minilab®, Raman spectroscopy, NIR etc to help regularly monitor the quality of medicines in the country.

## ANNEXES

### Annex 1: List of Brands sampled

| Brand Name | Inn Name | Batch No. | Manufacturer Name | Address of Manufacturer | Nature Of OOS | Source |
|---|---|---|---|---|---|---|
| Alimox | Amoxicillin Trihydrate | 01599ams | Sphinx Pharmaceuticals Ltd | Kenya | Physical Appearance | OOS |
| Amitrip Tablets | Amitriptyline | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |
| Chlorpromazine Tablets | Chlorpromazine | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |
| Ciprolab Tablets | Ciprofloxacin | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |
| Cloxam DPS | Ampicillin Trihydrate | Other Batches | Sphinx Pharmaceutical Ltd | Kenya | CMC defects | GMP Feedback |
| Daflon | Micronized Purified Flavonoid Fraction Diosmin, Flavonoids | 34291 | Servier Egypt Industries Limited | Egypt | Assay | OOS |
| Daflon | Micronized Purified Flavonoid Fraction Diosmin, Flavonoids | 33559 | Servier Egypt Industries Limited | Egypt | Assay | OOS |
| Dexatas | Glucose 5% | 24165 | Tasa Pharma | Kenya | Assay | OOS |
| Harteze Capsules | Rivaroxaban | Other Batches | Cosmos Pharmaceutical Ltd | Kenya | CMC defects | GMP Feedback |
| Ibuflam Plus Suspension | Ibuprofen + Paracetamol | Other Batches | Biodeal Laboratory Ltd | Kenya | CMC defects | GMP Feedback |
| Ifas | Ferrous Sulphate and Folic Acid | 26016 | Treffer Pharmaceuticals | India | Assay | OOS |
| Leocef DPS | Cefalexin | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |

| Brand Name | Inn Name | Batch No. | Manufacturer Name | Address of Manufacturer | Nature Of OOS | Source |
|---|---|---|---|---|---|---|
| Magnesium Sulphate | Magnesium Sulphate | | Laboratory & Allied Ltd | Kenya | | GMP Feedback |
| Medopress Tablets | Methyldopa | Other Batches | Cosmos Pharmaceutical Ltd | Kenya | CMC defects | GMP Feedback |
| Paradol Oral Solution | Paracetamol | Other Batches | Dinlas Pharmaceutical Ltd | Kenya | CMC defects | GMP Feedback |
| Paratal Tablets | Paracetamol | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |
| Racycline Ointment | Tetracycline | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |
| Triofen | Ibuprofen | Other Batches | Zain Pharma Limited | Kenya | Physical Appearance | OOS |
| Zahro | Hydrochlorothiazide | T25c016 | Zain Pharma Limited | Kenya | Physical Appearance | OOS |
| Zerocin DPS | Azithromycin | Other Batches | Laboratory & Allied Ltd | Kenya | CMC defects | GMP Feedback |
| Zolas Oral Suspension | Albendazole | Other Batches | Dinlas Pharmaceutical Ltd | Kenya | CMC defects | GMP Feedback |

## Annex 2: Sample Collection Form


**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 Name: e.g., Amoxicillin | | | |
| Brand (Product name): (If applicable e.g., Amoxil) | | | |
| Dosage Form: (E.g., tablets/ dispersible 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 #: | | Date of Manufacture: | |
| (e.g., CF2012A4) | | (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 3: Facility Details Form


**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 a fridge thermometer? YES NO | |
| What was the temperature recording? | |
| Did the storage area have a wall thermometer or thermohygrometer?<br>YES NO | |
| Storage Temperature:<br>(In area/ room where sample was picked e.g., 26.5° Celsius | |
| % Relative Humidity:<br>(In area/ room where sample was picked e.g., 56.5%) | |
| Did the storage area have the temperature chart?<br>YES NO | |

Name & Signature of sample collectors:

1._____

2._____

***Note:***

a) *Samples collected must remain in their original containers, intact and unopened.*
b) *This Sample Information Collection form should always be kept with the sample collected.*
c) *Proper sampling procedures should be followed.*
d) *The excel database should be properly filled*
e) ***Faith-based** health care facilities shall be **categorized as private***

## Annex 4: Product Information Review Form

REPUBLIC OF KENYA

**MINISTRY OF HEALTH**
**PHARMACY AND POISONS BOARD**

| | |
|---|---|
| **Unique sample code** | |
| **Product name:** | |
| **INNs:** | |

| **2- Primary packaging** | **Information present on the label** | | | | |
|---|---|---|---|---|---|
| Product name | YES | | NO | | |
| Strength | | | | | |
| Unit dose per blister or container stated | YES | | NO | | |
| Batch number | YES | | NO | | |

| **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 | ……<br>……<br>…… | | | | |
| Storage conditions | …… | | | | |
| Labelling | YES | | NO | | |

| | |
|---|---|
| Language<br>English /<br>Kiswahili | |

| | | | |
|---|---|---|---|
| Manufacturing date | YES | NO | |
| Expiry date | YES | NO | |
| Manufacturer name<br>(Specify only if different from the external packaging under point 1) | YES<br>…… | 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<br>……<br>…… | NO | |
| Storage conditions (Specify only if different from the external packaging under point 1) | YES<br>……<br>…… | NO | |

## Annex 5: Visual and physical inspection and Minilab® results form


**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.<br>Have any corrections and/or additions been made to Sample Collection Form (Annex 2):<br>☐ 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)<br>1. _____<br>2. _____<br>3. _____ | Did the drug pass the disintegration test?<br>☐ Yes ☐ No | |

| **TEST 3: TLC** | |
|---|---|
| Did the sample have a spot? ☐ Yes | Intensity of sample spot compared to standard: |

| | |
|---|---|
| ☐ No<br>Rf Standard: _____<br>Rf Sample: _____<br>Rf % Sample difference:[5] _____ | Were there any contaminants/impurities present?<br>☐ Yes ☐ No<br>Observations: _____ |
| **FINAL RESULTS** | |
| Reason: _____<br>Reason: _____ | |
| How many units are remained after basic tests? _____ | |
| **REPORT REVIEWED BY[6]:** | |
| Name: _____<br>Date: _____ | Signature: _____ |

[5] Rf % Sample Difference =

This formula 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 = 6

If applicable

## ANNEX 6: LIST OF CONTRIBUTORS

**Table 10 List of Contributors**

| S/N | Name | Department | Designation |
|---|---|---|---|
| 1. | Dr Ahmed I. Mohamed | CEO office | CEO |
| 2. | Dr. Christabel Khaemba | Products Safety | Deputy Director Products Safety |
| 3. | Dr Edward Abwao | Products Safety | Head, PMS |
| 4. | Dr. Onesmus Saidimu | Products Safety | Principal Regulatory Officer |
| 5. | Dr Bramuel Tongola | CEO office | Technical Advisor |
| 6. | Dr. Roselyne Muhia | Products Safety | Regulatory Officer |
| 7. | Dr. Ruth Njoga | Products Safety | Regulatory Officer |
| 8. | Dr. Silas Ireri | Products Safety | Regulatory Officer |
| 9. | Dr. Asfat Abdalla | Products Safety | Regulatory Officer |
| 10. | Dr. Wycliffe Miyere | Products Safety | Regulatory Officer |
| 11. | Dr. Godwin Seki | Products Safety | Regulatory Officer |
| 12. | Dr. Valerie Khamira | Marketing Authorization | Regulatory Officer |
| 13. | Michael Bugigi | Quality Control | Regulatory Officer |
| 14. | Luke Maiyo | Quality Control | Regulatory Officer |

## Sample Collection Photos








.

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