
**MINISTRY OF HEALTH**

# REPORT ON POST-MARKETING QUALITY SURVEILLANCE OF SELECTED HEALTH PRODUCTS AND TECHNOLOGIES ON THE KENYAN MARKET

**OCTOBER 2023**

**Acknowledgements**

This report presents the findings from post-market quality surveillance of selected health products and technologies used in Kenya's market. The survey was conducted in collaboration between the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL), Community pharmacies, Public and private hospitals, FBOs, County governments and the Kenya Medical Supplies Authority (KEMSA).

The authors of this report would like to thank the CEO, Pharmacy and Poisons Board, the Director, NQCL, CEO KEMSA, the National Pharmacovigilance and Post-Marketing Surveillance (PV/PMS TWG) and the County Governments, for facilitating this noble activity. The invaluable contribution of sample collectors and respondents without whom the survey would not have been a success is acknowledged. Special gratitude to Dr Karim Wanga for planning and coordinating the entire PMS activity.

**List of contributors**

| Contributors | Institution |
|---|---|
| Dr Fred Siyoi | CEO, PPB |
| Dr Serah Muteru | Ag. Director, NQCL |
| Dr Antony Toroitich | PPB |
| Dr Karim Wanga | PPB |
| Dr Matthew Kwena | NQCL |
| Dr Ernest Mbae | NTLD-P |
| Abdiwahab Maalim | PPB |
| Enow Haji | PPB |
| Dr Onesmus Saidimu | PPB |
| Dr Tom Kauki | PPB |
| Dr Peter Ngumo | NQCL |
| Dr Pamela Nambwa | PPB |
| Abdinassir Sheikh | PPB |
| Charles Odhiambo | NQCL |
| Luke Maiyo | PPB |
| Beatrice Obinge | PPB |
| Ruth Ndanyo | NQCL |
| Dr Mercy Siyoi | County government of Kajiado |
| Gladys Bogonko | NQCL |
| Michael Bugigi | PPB |
| Dr Azaria Tola | PPB |
| Dr Donald Ratemo | County government of Kisii |
| Beatrice Rosanna | KEMSA |
| Dr Peter Ndwigah | University of Nairobi |
| Dr Ruth Njoga | PPB |
| Dr Roselyne Njoki | PPB |
| Dr Silas Gitonga | PPB |

**Table of Contents**

Acknowledgements ..... i
List of contributors ..... ii
Definitions of Key terms ..... vii
Executive summary ..... 1
1.0 INTRODUCTION ..... 2
1.1 Background ..... 2
1.2 Existing legal framework and government agencies ..... 4
1.3 Problem statement ..... 5
1.4 Survey Justification ..... 6
2.0 OBJECTIVES OF THE SURVEY ..... 11
2.1 Main Objective ..... 11
2.2 Specific Objectives ..... 11
3.0 METHODOLOGY ..... 11
3.1 Survey scope and duration ..... 11
3.2 Survey design ..... 12
3.3 Selection of HPTs for inclusion in the survey ..... 12
3.4 Selection of sampling site ..... 13
3.5 Selection of sampling outlets (Facilities) ..... 14
3.6 Sample size ..... 15
3.7 Definition of a sample ..... 16
3.8 Sampling plan ..... 17
3.9 Laboratory analysis ..... 20
4.0 RESULTS ..... 22
4.1 Health products and technologies that were sampled ..... 22
4.2 Sampling sites (healthcare facilities/ pharmaceutical outlets) ..... 25
4.3 Samples submitted for compendial testing ..... 26
4.4 Laboratory Analysis Results ..... 29
5.0 DISCUSSION ..... 58
6.0 RECOMMENDATION ..... 58

7.0 CONCLUSION ..... 59
8.0 REFERENCES ..... 59
9.0 ANNEXES ..... 62
Annex 1: Sample Collection Form ..... 62
Annex 2: Facility forms: Facility Details Form ..... 64
Annex 3: Visual and physical inspection and MiniLab results form ..... 66
Annex 4: Product information review (PIR) form ..... 70
Annex 5: Report format for PMS field activity ..... 72
Annex 6: List of sampling facilities ..... 74

**List of Tables**

Table 1: List of Health products and technologies selected for inclusion in the quality survey ..... 12
Table 2: Number of samples per drug product ..... 15
Table 3: Number of samples per medical device ..... 16
Table 4: The molecules and test parameters that were analyzed ..... 21
Table 5: Samples collected distributed by counties and therapeutic indications ..... 24
Table 6: Number of samples collected from the selected counties ..... 26
Table 7: Secondary sampling matrix ..... 27
Table 8: Samples subjected to verification using MiniLab technique in the PPB-QC Lab ..... 30
Table 9: Summary of the MiniLab results ..... 30
Table 10: Summary of compliance status of health products ..... 41
Table 11: Analysis Results for Paracetamol suspension ..... 42
Table 12: Analysis Results for Losartan tablets ..... 43
Table 13: Analysis results for Doxorubicin injection ..... 45
Table 14: Analysis Results Omeprazole capsules ..... 46
Table 15: Analysis Results for Amoxicillin capsules ..... 47
Table 16: Analysis Results for Amoxicillin Dispersible Tablets (DT) ..... 48
Table 17: Analysis Results for Cetirizine tablets ..... 49
Table 18: Analysis Results for Enalapril tablets ..... 51
Table 19: Analysis Results for Paracetamol tablets ..... 52
Table 20: Analysis Results for Lorsartan tablets ..... 54
Table 21: Analysis Results for Levonorgestrel tablets ..... 55
Table 22: Analysis Results for Male latex condoms ..... 56

**List of Figures**

Figure 1: Graph showing the global status of antimicrobial resistance ..... 8
Figure 2: Graphs showing antimicrobial susceptibility / Resistance patters of different pathogens against different antibiotics ..... 9
Figure 3: Sample distribution by therapeutic indication ..... 25
Figure 4: Graph on distribution of secondary samples disaggregated by county ..... 28
Figure 5: Sample distribution by field screening using MiniLab technique ..... 29
Figure 6: Samples that were tested using MiniLab technique ..... 39
Figure 7: Results of field screening using MiniLab technique ..... 39
Figure 8: Results of verification screening using MiniLab technique ..... 40

**Acronyms and Abbreviations**

| | |
|---|---|
| AMR | Antimicrobial Resistance |
| CoA | Certificate of Analysis |
| EAC | East African Community |
| GSMS | Global Surveillance and Monitoring System |
| IGAD | Intergovernmental Authority on Development |
| INN | International Non-Proprietary Name |
| KEMSA | Kenya Medical Supplies Authority |
| LMIC | Low- and Middle-Income Countries |
| MFL | Master Facility List |
| MOH | Ministry of Health |
| NEML | National Essential Medicines List |
| NLS | National Laboratory Services |
| NMRA | National Medicines Regulatory Authority |
| NQCL | National Quality Control Laboratory |
| OOS | Out of Specification |
| PMS | Post Marketing Surveillance |
| PPB | Pharmacy and Poisons Board |
| PV/PMS TWG | Pharmacovigilance and Post-marketing surveillance technical working group |
| SF | Substandard and falsified medical products |
| TLC | Thin Layer Chromatography |
| UHC | Universal Health Coverage |
| WHO | World Health Organization |

**Definitions of Key terms**

| | |
|---|---|
| Falsified Medical Products | Products that deliberately or fraudulently misrepresent their identity, composition or source. |
| Medical Products | Includes medicinal products and medical devices. |
| Health Technologies | The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems to solve a health problem and improve quality of lives. |
| Post Market Surveillance | Refers to all the processes that are carried out to continuously track/ monitor, quality, safety and efficacy of medicines after-market authorization. |
| Product | In this report, a product is defined as a brand with different or similar active pharmaceutical ingredient but with unique dosage forms and strength. |
| Product Registration | Evaluation and approval by the national medicines regulatory authority to market the product in a particular jurisdiction. Market authorization of health products and technologies. |
| Recall | The removal of specific batch/ batches of a health product/technology from the market for reasons relating to deficiency in the quality, safety, efficacy or effectiveness. |
| Substandard products | Authorized medical products that fail to meet either their quality standards or specifications or both. They may also be referred to as being “out of specifications” |
| Universal Healthcare Coverage | Provision of quality health services (promotive, preventive, curative, preventive, rehabilitative and palliative care) to all people and communities without suffering financial hardship. |

**Executive summary**

The Pharmacy and Poisons Board (PPB) in collaboration with the National technical working group on pharmacovigilance and post-marketing surveillance (PV/PMS TWG) implemented post-marketing quality surveillance of selected health products and technologies (HPTs) circulating on the Kenyan market. The product categories that were sampled and tested were; Antimicrobials (Amoxicillin and ciprofloxacin), Anti-cancer agents (Doxorubicin), Antihypertensives (Enalapril and Losartan), Analgesics (Paracetamol), contraceptives. (Levonorgestrel), Anti-histamines (Cetirizine) and anti-ulcer medicines (Omeprazole). The medical devices include the male latex condoms.

The counties and healthcare facilities where samples were collected from were determined based on risk-ranking using an excel based medicines-risk based surveillance (MedRS) tool.

The samples were collected from the following fifteen (15) counties; Bungoma, Busia, Garissa, Kajiado, Kiambu, Kisumu, Kwale, Lamu, Mandera, Migori, Mombasa, Nairobi, Nyeri, Siaya and Vihiga

A total of two hundred and seventy nine (279) were collected from 142 pharmaceutical outlets and healthcare facilities. All samples were subjected to visual and physical inspection while 171 samples were subjected to MiniLab analysis. All samples complied with the parameters for visual and physical inspections. Similarly; all samples that were analyzed using MiniLabs complied with specifications for all the test parameters analyzed. A total of 72 samples were subjected to compendial testing at the National quality control laboratory (NQCL) and all except one sample complied with specifications for all the test parameters analyzed. The sample that failed to comply is Enril-5 (Enalapril 5 mg) , batch No. KN532 which is manufactured by Prism Lifesciences Limited, India. The product failed assay test ( 81.5%, while the specification limits are 90.0 – 110). The PPB initiated immediate recall of the product from the Kenyan market.

The continuous monitoring of the quality of HPTs in the Kenyan market is critical in ensuring and assuring their safety and efficacy and hence achieving desirable patient outcomes as well as enhancing confidence in the healthcare delivery system.

## 1.0 INTRODUCTION

### 1.1 Background

The Pharmacy and Poisons Act, CAP 244 of the laws of Kenya, mandates the Board to regulate the trade in health products and technologies. Sections 3(A)(f) and 3B(2)(k, l, and m) mandate the Board to implement market surveillance activities to monitor the quality, safety, and efficacy of health products and technologies circulating in Kenya.

Health products and technologies are essential components of healthcare service delivery[1]. Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality, and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC), and Sustainable Development Goal 3.b emphasizes the need to develop medicines to address persistent treatment gaps (Sachs). Access to good quality health products and technologies increases public confidence in healthcare systems[2].

The quality of medical products and health technologies is an important factor in disease prevention and treatment. Quality is fundamental to their effectiveness and safety, hence a healthy outcome for the patient. Ensuring

[1] (Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B., & Van Damme, W.)

[2] (Kruk, M. E., Gage, A. D., Arsenault, C., Jordan, K., Leslie, H. H., Roder-DeWan, S., ... & Pate, M.)

quality requires the concerted effort of all stakeholders in the entire lifecycle of health products and technologies [3].

A very important component of ensuring that the public gets quality medicines is by establishing and implementing a Post-market surveillance (PMS) system that involves monitoring the safety and quality of a pharmaceutical drug or medical device after it has been released on the market. PMS enables the detection of Substandard and Falsified (SF) products, registration status, and the effects of storage conditions on the quality and stability of the products [4].

The Pharmacy and Poisons Board (PPB) is responsible for regulating the trade of HPTs in Kenya. The core responsibilities of the PPB include ensuring the availability of high-quality, safe, and effective HPTs. This is achieved through evaluating and registering medical products, monitoring the quality, safety, and efficacy of these products after authorization, regulating the promotion of HPTs, encouraging their rational use, and conducting inspections and surveillance activities.

Through PMS, the PPB can detect substandard and falsified (SF) products, assess the registration status, and evaluate the effects of storage conditions on product quality and stability. Substandard medical products, often referred to as "out of specification," are authorized by the National Medicines Regulatory Authority (NMRA) but fail to meet quality standards or specifications. Falsified medical products intentionally misrepresent their identity, composition, or source, while unregistered products have not undergone evaluation and approval by the NMRA for their respective markets.

According to the World Health Organization (WHO), it is estimated that 1 in 10 medicines in low- and middle-income countries (LMICs) is either substandard or

[3] (Porter, M. E., & Teisberg, E. O.)
[4] (Newton, P. N., Lee, S. J., Goodman, C., Fernández, F. M., Yeung, S., Phanouvong, S., ... & White, N. J.; Kramer, D. B., Baker, M., Ransford, B., Molina-Markham, A., Stewart, Q., Fu, K., & Reynolds, M. R.)

falsified. The prevalence of SF medicines varies across countries and regions. Surveillance in Africa and Asia has reported a higher prevalence of substandard medicines in West Africa compared to East Africa. The exact burden of SF medical products in the East African region is unknown, but it is estimated that around 10% of globally traded medicines are SF, with an even higher prevalence in LMICs. Access to high-quality health products and technologies enhances public confidence in healthcare delivery systems.

Post-marketing surveillance (PMS) is an important regulatory function in monitoring the quality of health products and technologies that are available to the Kenyan public. The PPB, in collaboration with DNMP and NQCL, in July 2023 set out to survey the quality of HPTs circulating in the Kenyan market. The selection of drugs for sampling was done using the Medicines Risk-based Surveillance (MedRS) tool, applying an Excel-based tool.

### 1.2 Existing legal framework and government agencies

Article 43 (1) (a) of the constitution of Kenya 2010 provides that every person has the right to the highest attainable standard of health, which includes the right to health care services. Highest standards of health are only attainable if the Health products and Technologies in the market are of the right quality, efficacy, and safety.

Health Act No. 21 of 2017, section 62 (Act of Parliament) establishes a single regulatory body for regulation of health products and health technologies. Among the functions of the regulatory body under the (Health Act No. 21 of 2017, section 63(1)(e) is to conduct post marketing surveillance for quality, safety and disposal of health products and health technologies.

The pharmacy and poisons act (Cap 244) is the act of parliament to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons. The Pharmacy and Poisons Board (PPB) is the National Health products and Technologies Regulatory Authority established in 1957 by an Act of Parliament; the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya.

Sections 3 (A)(f), 3B (2) (k, l, and m) of CAP 244 of the Laws of Kenya mandates the Board to implement post-marketing surveillance to monitor quality, safety and efficacy of HPTs circulating in Kenya

Section 35D of the Pharmacy and Poisons act establishes the national drug quality control laboratory (NQCL). It is the official Health products and Technologies control laboratory and was established in 1992 through an amendment of the Pharmacy and Poisons Act, Cap. 244, Laws of Kenya. The 1992 amendment mandates NQCL to carry out quality control testing of all Health products and Technologies in the country on behalf of the Ministry of Health and the Government of Kenya. The NQCL is both WHO prequalified and ISO 17025 accredited.

The Kenya National Pharmaceutical policy is the overall guiding policy on HPTs with the goal of achieving universal access to quality assured, safe, and efficacious HPTs in Kenya.[5] The Ministry of Health (MOH) provides overall stewardship of HPTs in line with Kenya Health policy and the Health Act, 2017.

### 1.3 Problem statement

The World Health Organization (WHO) estimates that approximately 10% of health products in low- and middle-income countries (LMICs) are either substandard or falsified. Since 2013, WHO has received 1,500 reports of such cases, with antimalarial and antibiotic products being the most frequently reported. The majority of these reports (42%) originate from the WHO African Region, with 21% from the WHO Region of the Americas and another 21% from the WHO European Region[6].

Substandard and falsified health products are not confined to high-value medicines or well-known brand names and are split almost evenly between

[5] Sessional paper 4 0f 2012

[6] World Health Organization *A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products*. Geneva, Switzerland: World Health Organization; 2017.

generic and patented products. The prevalence of substandard and falsified medicines is known to vary between different countries and regions; the prevalence of poor-quality medicines was much higher in West Africa than in East Africa.

In the last one year, the PPB has received complaints on several products in the market. These complaints range from poor quality products, (capsules clamping, layering of Fixed Dose Combination tablets, look-alike (similar packaging) to suspected therapeutic ineffectiveness.

### 1.4 Survey Justification

The evaluation and registration of medicines is an important function to control the quality, safety and efficacy of HPTs. In addition, it is critical to ensure and assure quality, safety and efficacy of HPTs post-registration. This requires continuous monitoring through both active and pro-active post marketing surveillance that is aimed at ensuring the quality attributes and performance of the HPTs are consistent throughout their lifecycle as well as predicting and preventing potential risks that may pose threats to public health.

The selection of health products and technologies for inclusion in the survey considered public health impact, extent of use of the products, market complaints and historical quality data. The selected HPTs are Amoxicillin dispersible tablets & Amoxicillin capsules, Ciprofloxacin tablets, Doxorubicin injection, Enalapril tablets, Losartan tablets, Paracetamol suspension & Paracetamol tablets, Cetirizine tablets, Levonorgestrel tablets, Omeprazole capsules, male latex condoms and syringes (with needles).

Antimicrobial agents are the cornerstone of healthcare delivery systems for the treatment of infections both in humans and animals and prophylaxis in surgery. The effectiveness of antimicrobial agents has been compromised by increasing levels of resistance by common pathogens. The presence of substandard or falsified (SF) antimicrobials is associated with increased risk of antimicrobial

resistance (AMR). Other causes of AMR are inappropriate use, overuse, misuse, abuse and poor infection prevention & control (IPC) practices.

The AMR Global Report on Surveillance by the World Health Organization (WHO) showed high resistance rates in bacterial pathogens frequently implicated in common hospital, community and food-chain-related infections in all the WHO regions. Five out of six WHO regions reported >50%. Resistance to third-generation cephalosporins and fluoroquinolones in Escherichia coli, 6/6 and 2/6 regions reported >50%. Resistance to third generation cephalosporins and carbapenems respectively, in Klebsiella pneumoniae, while 5/6 regions reported >50% resistance to methicillin in staphylococcus aureus as examples of common causative bacteria in hospitals and the community.

All the six WHO regions further reported > 25 % resistance to penicillin in streptococcus pneumoniae, 3/6 regions reported > 25 % resistance to fluoroquinolones and third-generation cephalosporins in non-typical Salmonella and Neisseria gonorrhea, respectively and 2/6 regions reported > 25 % resistance to fluoroquinolones in Shigella species as examples of causative bacteria in largely community settings.

Another study describing antimicrobial resistance (AMR) to commonly used antibiotics has been reported in East Africa with 50% – 100% resistance to ampicillin and cotrimoxazole infections reported. There is growing resistance to Gentamicin (20% – 47%) and relatively high levels of resistance to Ceftriaxone (46% – 69%) among Gram-negative infections. Much of the resistance was reported to be in Klebsiella species and Escherichia coli.[1]

The Ministry of Health (MOH), Kenya report on AMR shows that there is 65% resistance by Escherichia coli to ciprofloxacin (human health) and 22% resistance to ciprofloxacin by the staphylococcus aureus in animal health.

A study carried out in Kenya on National level estimation of antimicrobial consumption (AMC), for the period 2018 to 2021 found that beta-lactamase antibacterials, penicillins were the most consumed antibiotics (J01, anti-

infectives for systemic use), accounting for 65.88% of total consumption. The beta lactam antibacterials (others) were second (16.18%) while macrolides, lincosamides and. Streptogramins were third at 5.9%.

The same study reported that a total of six drugs accounted for 75% drug utilization (DU75) of the total drug utilization of antibiotics (J01) for the reporting period, 2018 to 2021. They drugs are Amoxicillin (32.11%), Benzylpenicillin (19.48%), Ceftriaxone (11.05%), combination of penicillins (6.51%), Azithromycin (4.65%), Amoxicillin combination with beta-lactamase inhibitors (4.39%).

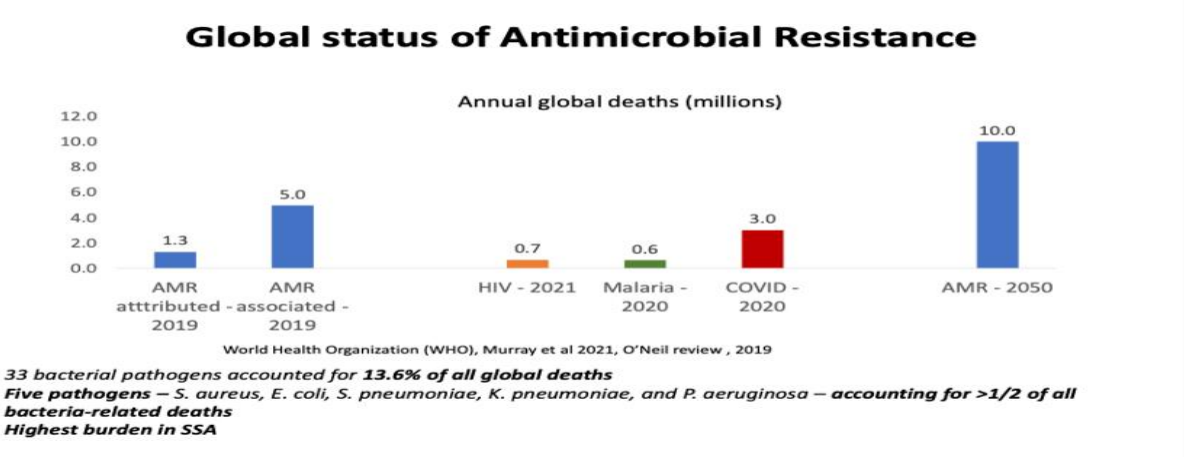


**Figure 1:** Graph showing the global status of antimicrobial resistance

Ministry of Health, Kenya, AMR report

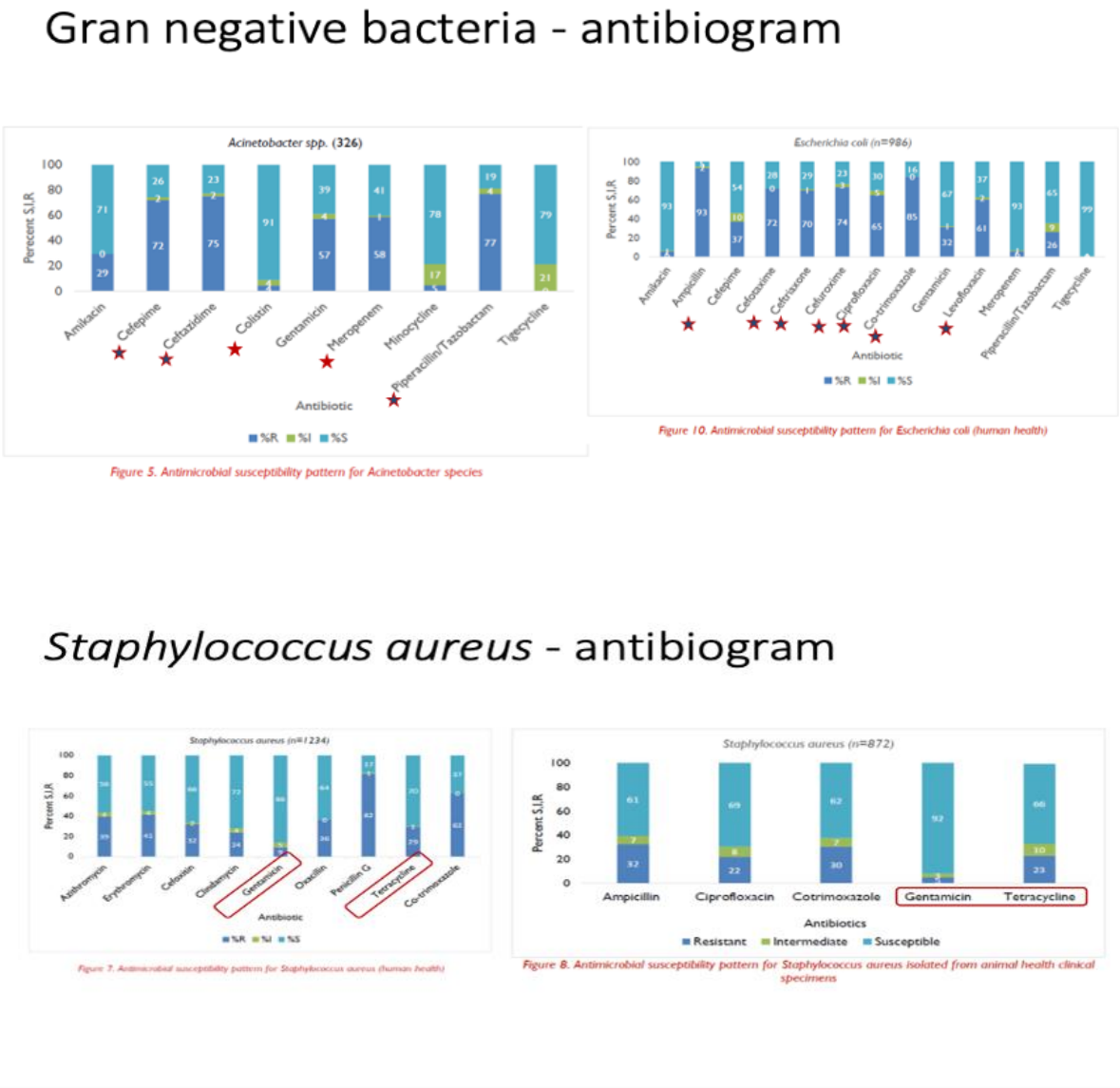


Figure 5. Antimicrobial susceptibility pattern for Acinetobacter species

Figure 10. Antimicrobial susceptibility pattern for Escherichia coli (human health)

Figure 7. Antimicrobial susceptibility pattern for Staphylococcus aureus (human health)

Figure 8. Antimicrobial susceptibility pattern for Staphylococcus aureus isolated from animal health clinical specimens

**Figure 2:** Graphs showing antimicrobial susceptibility / Resistance patters of different pathogens against different antibiotics

Fever is a common symptom in children aged five years and below and can cause morbidity and mortality if it is not managed. Analgesics and antipyretics such as paracetamol are critical in management of pain and pyrexia in children. Paracetamol is also widely used as analgesic in adults and since it is categorized as over the counter medication, it is easily accessed by the general population.

In view of the above, it is important to ensure and assure quality of these products in order to protect health and safety of the public.

Antihistamines such as cetirizine are critical in management of allergic reactions and conditions. Cetirizine is widely used and easily accessed over the counter by the public. The main indications are allergic rhinitis, urticaria, allergic conjunctivitis among others. The PPB is in receipt of market complaints on quality on some products of cetirizine circulating in the Kenyan market. The nature of complaints is powdering and color change.

The PPB has also received several market complaints on quality of some products of omeprazole on the Kenyan market

Cancer is the third leading cause of mortality both globally while it is the second leading cause of death from non-communicable diseases in Kenya, second to cardiovascular diseases. Prostate cancer is the most common among males followed by cancer of esophagus, colorectal cancer, non-hodgkins lymphoma and stomach cancer. Breast cancer is the most frequent cancer in females, followed by cervical cancer, esophagus, colorectal and ovarian cancer.

The national cancer taskforce report, July 2022 recommended strengthening of quality assurance and quality control mechanisms for HPTs used for cancer treatment and care.

In this regard, the PV/PMS TWG selected doxorubicin for inclusion in the quality survey. Doxorubicin is used alone or in combination in management of breast cancer, gastric cancer, hodgkins lymphoma, non-hodgkins lymphoma, ovarian cancer, large B-cell lymphoma, kaposi sarcoma, follicular lymphoma, osteosarcoma, acute lymphoblastic leukemia, burkitt lymphoma, multiple myeloma among other indications. In addition, the National Cancer Control Program has received complaints related to quality of doxorubicin products. The nature of the complaints is the powder does not reconstitute as expected and discoloration of the solution after reconstitution.

A study by Mohammed S F et al found that the overall age-standardized prevalence of hypertension was 24.5% (95% CI, 22.6-26.6%). Other studies have shown that deaths due to NCDs have risen from 35% to 45% in 2010, with hypertension being a major contributor to this trend. The PV/PMS TWG selected Losartan and Enalapril for inclusion in the quality survey. The two molecules are the mainstay for management of hypertension in Kenya. Based on historical quality data (the RRI PMS report of 2019), some enalapril products failed to comply with specifications on test parameters analyzed like assay. It is important to undertake continuous quality monitoring of these products to check compliance with market authorization requirements.

## 2.0 OBJECTIVES OF THE SURVEY

### 2.1 Main Objective

To conduct risk-based quality survey of selected health products and technologies available at various distribution levels in the Kenyan market.

### 2.2 Specific Objectives

1. To determine the registration and retention status of selected HPTs sampled in the quality survey
2. To assess the quality attributes of HPTs through visual & physical inspection and laboratory testing
3. To determine the prevalence of substandard and falsified (SF) HPTs circulating in the Kenyan market in view of implementing regulatory actions
4. To provide evidence-based recommendations based on findings from the quality survey

## 3.0 METHODOLOGY

### 3.1 Survey scope and duration

This was a risk-based quality survey covering different tiers of healthcare facilities drawn from both the public and private sectors. The sampling sites included the central procurement agencies, warehousing facilities, wholesalers,

retail pharmacies, healthcare facilities at National, County, Sub- County levels across the country as determined by the Medicines Risk-based Surveillance (MedRS) tool. The data and samples collection activity was implemented for a period of seven (7 days) while the MiniLab and compendial testing activities was implemented over a period of fiive working days. The list of counties and facilities where samples were collected from is attached in ***annex 6.***

### 3.2 Survey design

This was a cross-sectional survey that employed a descriptive and quantitative data collection methods

### 3.3 Selection of HPTs for inclusion in the survey

The survey focussed on HPTs that were selected based on an established criterion as follows;

a. Consumption data of the medicines
b. Public health importance of the medicines including the diseases for which the molecules are indicated
c. National level antimicrobial resistance (AMR) data for Kenya
d. The National Essential Medicines List (NEML) from the partner states
e. Market complaints received by PPB on the quality of the medicines
f. Historical quality data on the medicines

The following HPTs (Table 1) were selected by the National PV/PMS TWG for sampling and testing

**Table 1:** List of Health products and technologies selected for inclusion in the quality survey

| S/N | Molecule | Therapeutic Category | Formulations |
|---|---|---|---|
| 1 | Amoxicillin | Antibiotic | Dispersible tablets |
| 2 | Amoxicillin | Antibiotic | Capsules |

| S/N | Molecule | Therapeutic Category | Formulations |
|---|---|---|---|
| 3 | Ciprofloxacin | Antibiotic | Tablets |
| 4 | Doxorubicin | Anticancer | Injection |
| 5 | Enalapril | Antihypertensive | Tablets |
| 6 | Losartan | Antihypertensive | Tablets |
| 7 | Paracetamol | Analgesic | Suspension |
| 6 | Paracetamol | Analgesic | Tablets |
| 8 | Cetirizine | Antihistamine | Tablets |
| 9 | Levonorgestrel | Contraceptive | Tablets |
| 10 | Omeprazole | Anti-Ulcer | Capsules |

**Medical devices**

| S/N | Name of medical device |
|---|---|
| 1 | Male latex condoms |
| 2 | Syringes + (Needles) |

### 3.4 Selection of sampling site

The selection of survey sites was determined using a risk-based approach by the MedRS tool. The tool was applied to determine risk-ranking of counties (regions), sub-counties and sampling facilities for each of the HPTs selected except omeprazole, paracetamol, Levonorgestrel, syringes and male latex condoms. The following were taken into consideration when selecting the sampling sites;

a. Areas where product complaints have been reported
b. Geographical location: Proximity to the ports of entry.
c. Areas where disease prevalence is high.
d. Areas with poor accessibility to products.
e. Areas with high population density and low income

**The following counties were targeted for sampling;** Nairobi, Mombasa, Kajiado, Garissa, Kisumu, Busia, Mandera, Isiolo, Wajir, Baringo, Vihiga, Tharaka-Nthi, Elgeyo-Marakwet, Lamu, Uasin Gishu, West-Pokot, Kisii, Marsabit, Nandi, Samburu, Turkana, Kiambu, Laikipia, Tana-River, Migori, Kwale, Muranga and Bungoma. In addition, for purposes of sampling of omeprazole, levonorgestrel, syringes and male latex condoms, the following additional counties shall be included; Nakuru, Machakos, Makueni, Kilifi, Meru, Siaya, Kericho and Nyeri.

### 3.5 Selection of sampling outlets (Facilities)

The MedRS tool was applied for selection of targeted sampling outlets based on risk-ranking. The HPT samples were collected at different tiers of healthcare facilities across the distribution chain both in public and private sector. The selected facilities fall under the following categories;

a. Points of entry: Warehouses of Importers/ manufacturers, central and regional medical stores, NGO central stores, procurement centers
b. Regulated wholesalers and distributors
c. Regulated dispensaries: This refers to all facilities both public and private from where patients access medicines i.e retail pharmacies, hospitals,

health centers, dispensaries, hospitals, clinics, maternity Homes, treatment centers.

### 3.6 Sample size

The sample size of medicines and/or facilities was calculated using Cochran formula:

$$n = \frac{n_o}{1 + \frac{n_o - 1}{N}}$$

$$n_o = \frac{Z^2 p(1-p)}{e^2}$$

Where:

P is the prevalence of the poor medicines that is estimated percent of the medicines that are believed to be of poor quality (it is an estimate of the true value). This value can be based on historical data, market intelligence or other information. Without any prior knowledge, P= 0.5 will give the most conservative estimate of the sample size (largest).

The critical value (Z) is the confidence level or the risk of rejecting null hypothesis about the true prevalence of poor medicines. Z(CI) is 1.96(95%), 1.64(90%) and 1.28(80%) confidence level.

The sample size formula is incorporated in the online MedRS Tool and it eventually computes the samples size taking into consideration various risks factors. The MedRS randomizes the facilities to be sampled. The actual number of samples to be collected was however adjusted based on the availability of resources, logistical and practical considerations. Hence based on these analyses, the total number of samples for each product categories targeted was captured in the sample table below;

**Table 2:** Number of samples per drug product

| S/N | Molecule | Therapeutic Category | Formulations | Number of samples |
|---|---|---|---|---|
| 1 | Amoxicillin | Antibiotic | Dispersible tablets | 40 |
| 2 | Amoxicillin | Antibiotic | Capsules | 40 |
| 3 | Ciprofloxacin | Antibiotic | Tablets | 40 |
| 4 | Doxorubicin | Anticancer | Injection | 10 |
| 5 | Enalapril | Antihypertensive | Tablets | 20 |
| 6 | Losartan | Antihypertensive | Tablets | 40 |
| 7 | Paracetamol | Analgesic | Suspension | 20 |
| 6 | Paracetamol | Analgesic | Tablets | 40 |
| 8 | Cetirizine | Antihistamine | Tablets | 40 |
| 9 | Levonorgestrel | Contraceptive | Tablets | 20 |
| 10 | Omeprazole | Anti Ulcer | Capsules | 40 |

**Table 3:** Number of samples per medical device

| S/N | Name of medical device | Number of samples |
|---|---|---|
| 1 | Male latex condoms | 15 |
| 2 | Syringes + Needles | 25 |

### 3.7 Definition of a sample

For purposes of this survey, a sample comprised of a given health product or health technology with the same product name, active ingredient, manufacturer, dosage form, unit dose (strength), Batch/Lot number, sampling outlet and packaging material.

At each sample collection outlet, a defined quantity of branded and/or generic presentations of the selected medical product that was available was collected, and the dosage units (tablets, capsules, vials, bottles) of one sample was drawn from the same batch.

**Number of units per sample**

The number of dosage units per sample collected followed the Good Laboratory Practices (GLP) for the quality control laboratory and were sufficient for;

a. The planned tests
b. Investigations of those found to be out of specification (OOS)
c. Retention samples to be used for retesting in case of disputes

### 3.8 Sampling plan

The sampling plan for this activity contained information on name (s) of HPTs to be sampled and tested, number of units per sample (batch) or quantity, dosage forms, strength and sampling site (s). The selection of sampling sites was based on risk-based criteria. The following was taken into consideration during preparation of sampling plan;

a. Identification of sample collection sites (counties / sub-counties and different tiers of sampling sites, both public and private. The tiers of sampling sites included the central procurement agencies, distributors / wholesalers, regulated dispensing points (hospital pharmacies and community retail pharmacies), unregulated dispensing points / informal sector (hospital pharmacies and community retail pharmacies), and internet sales of medical products.
b. Identification of HPTs to be sampled
c. Number of samples to be collected from each sampling outlet and substitution criteria for the sampling outlets
d. Defined timeframe for the sampling activity

e. Memorandum of understanding with quality control laboratory performing testing of the samples

### 3.8.1 Sample collection

Samples were collected from each of the selected outlets by a team of appointed sample / data collectors. A two-day training workshop was conducted for personnel participating in the sample and data collection and the analysts for the MiniLab activity. The participants were trained on the data and sample collection tools, the protocol on the quality survey (sampling techniques, sample handling, data entry, data management, MiniLab techniques)

The sample collection team carried out the following functions;

i. Collected the samples from the selected outlets
ii. Packed and labeled all samples collected in accordance with packaging and labeling instructions
iii. Completed the sample collection form for each sample
iv. Ensured shipment of the samples to the Pharmacy and Poisons Board offices in Nairobi.

### 3.8.2 Sample collection tools

The following tools were used for sample collection;

i. Sample collection form (Annex 02)
ii. Excel aggregation tool
iii. Sample packaging, labelling and transportation tools- Sample bags, markers, pens, note books, ball pens, marker pens, pencils, masking tapes and sample packing Carton

### 3.8.3 Sample collection logistics

The samples were shipped by either either land or air transport depending on accessibility of the sampling sites. The field activity was implemented over seven (7) days period followed by MiniLab activity for five (5) days. The samples were then submitted to the quality the control control laboratory for testing.

### 3.8.4 Sample collection instructions and precautions

The samples were collected in their original packages and for each sample collected, the sample collection form was duly filled. This was done in real time basis . In order to avoid confusion, each sample was identified using a unique sample code consisting of the name of the county, product code, date of sample collection and serialized number of the sample

a. The first three letters in the name of the county e.g.; KWA for Kwale County
b. Product code e.g.; KWA/AMXC/29.06.2023/003
c. Date of sampling e.g., 29.06.2023
d. Three-digit sequential serial number i.e.; 001, 002, 003

Each sample container / package (both primary and secondary package) was labeled with the unique sample code. The samples collected had at least six (6) months shelf-life at the time of collection. The samples collected were packed individually in special packaging materials with enclosed sample collection form

The samples were recorded using the sample collection form individually for each sample as well as the excel aggregation tool that was specifically designed for this survey. The followig facility details were also captured in the facility details form; Name and address of the sampling outlet, Name of county, MFL code where applicable, Name, telephone number and email address of the contact person

### 3.8.5 Handling, shipping and storage of samples

Samples collected were stored and transported in their original containers and in accordance with the manufacturer's storage conditions. Adequate measures were ttaken to ensure that samples reached the laboratory without any physical or chemical damage. Appropriate care was taken to provide adequate packaging to protect samples during transportation. All containers were sealed and appropriately labelled.

After completion of the sample collection activity, each team documented the general findings and observations of the activity in a summarized report in the format that was provided (***Annex 5).***

### 3.9 Laboratory analysis

Risk-based and three level testing approach was adopted for the analysis of samples. Level I (Visual and physical inspection and product information review) and level II a (MiniLab) screening of samples was be conducted at PPB regional offices while level II b (verification using MiniLab) was carried out at the PPB quality control laboratory.

The compendial testing was carried out at the National Quality Control Laboratory (NQCL) and assessed the test parameters determined by the National PV/PMS TWG and guided by the official compendia. In cases of non-conforming samples, the NQCL followed their internal procedude for investigation of out of specification (OOS) results.

#### 3.9.1 Confirmatory testing with compendial analysis

The compendial testing was done at the NQCL. The following criteria was applied in determining the samples that were submitted to the NQCL for analysis; analysis:

a) 100% of the samples that failed minilab screening

b) 100% of samples with doubtful minilab screening results.

c) 20% of samples which passed minilab screening tests

For the 20% that passed MiniLab tests, they were further subjected to secondary sampling to ensure diversification of brands, manufacturers, dosage forms, strengths and batches.

***Definitions:***
***Pass:*** *Conforms to all three (3) tests*
***Fail:*** *Does NOT conform to at least one (1) of the three (3) tests*
***Doubtful****: Conflicting or inconclusive results for at least one (1) of the three (3) tests*

Analysis request form was filled for each of the samples submitted for compendial analysis by the PPB QC laboratory. Samples were analyzed at the NQCL using methods obtained from official compendia, i.e., British Pharmacopoeia (BP 2022), United States Pharmacopoeia (USP 45 NF 40), International Pharmacopoeia (10th Edition) and International Standards Organization (ISO)

**Table 4:** The molecules and test parameters that were analyzed

| S/N | Molecule | Test parameters |
|---|---|---|
| 1 | Amoxicillin dispersible tablets | ID, Assay, Uniformity of Weight, Dissolution |
| 2 | Amoxicillin capsules | ID, Assay, Uniformity of weight, Dissolution |
| 3 | Ciprofloxacin tablets | ID, Assay, Uniformity of weight, Dissolution |
| 4 | Doxorubicin | ID, Assay, BET, Acidity/Alkalinity |
| 5 | Enalapril tablets | ID, Assay, uniformity of weight, Dissolution |
| 6 | Losartan tablets | ID, Assay, uniformity of weight, Dissolution |
| 7 | Paracetamol suspension | ID, Assay, Acidity / Alkalinity, Microbial load |
| 8 | Paracetamol tablets | ID, Assay, uniformity of weight, Dissolution |
| 9 | Omeprazole capsules | ID, Assay, uniformity of weight, Dissolution |
| 10 | Syringes | Acidity/Alkalinity, Package integrity, Needle, air leak test and Syringe Function Test. |
| 11 | Condoms | Quantity of Lubricant, Dimensions (Length), Freedom from holes, Burst Volume and pressure |

### 3.9.2 Certificate of Analysis

A Certificate of Analysis (CoA) that incorporates a summary of the actual method used to test each sample and the results obtained was issued for each sample analyzed.

### 3.9.3 Data Analysis, Interpretation and Dissemination

**Data quality assurance:** Data quality was assured through provision of training to sample and data collectors and by using a standard sample collection form as well as through supervision of the sample and data collection processes. All hard copies of recorded documents were compiled on the excel aggregation tool, cleaned and prepared for data analysis.

**Data interpretation:** Poor quality medicines may be substandard or falsified. In this survey, the WHO's definition was used to classify medicines as "Substandard or Falsified medicine". The regulatory status of products was evaluated based on PPB's internal policy.

**Data dissemination:** A detailed technical report of the survey was prepared and non-compliant results were immediately communicated to allow for timely and appropriate implementation of regulatory actions in-line with good regulatory practices.

## 4.0 RESULTS

### 4.1 Health products and technologies that were sampled

The product categories that were sampled include; Amoxicillin dispersible tablets & Amoxicillin capsules, Ciprofloxacin tablets, Doxorubicin injection, Enalapril tablets, Losartan tablets, Paracetamol suspension & Paracetamol tablets, Cetirizine tablets, Levonorgestrel tablets, Omeprazole capsules, male latex

condoms and syringes (with needles). A total of 279 Health products and technologies(Table 1, Figure 1 and Figure 2).

**Table 5:** Samples collected distributed by counties and therapeutic indications

| Row Labels | Analgesic | Anti ulcer | Anti-protozoal | Antibiotic | Anticancers | Antihistamine | Antihypertensive | ARVs | Contraceptive | Medical devices | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Bungoma | 2 | 1 | 1 | 4 | | 1 | 2 | 1 | 1 | 1 | 14 |
| Busia | 3 | 1 | 1 | 4 | | 2 | 2 | 1 | 2 | 1 | 17 |
| Garissa | 2 | 1 | 1 | 4 | | 1 | 3 | | 1 | 1 | 14 |
| Kajiado | 2 | 2 | 1 | 2 | | 2 | 2 | | 1 | 1 | 13 |
| Kiambu | 3 | 2 | 1 | 5 | | 3 | 4 | 1 | 4 | 4 | 27 |
| Kisumu | 5 | 2 | 2 | 5 | 1 | 1 | 1 | 1 | 3 | 1 | 22 |
| Kwale | 2 | 1 | 1 | 3 | | 1 | 2 | 1 | 1 | 1 | 13 |
| Lamu | 1 | 2 | | 6 | | 2 | 3 | | 1 | 1 | 16 |
| Mandera | 3 | 1 | 3 | 7 | | 2 | 2 | | 1 | 1 | 20 |
| Migori | 2 | 1 | 1 | 2 | | 1 | 2 | 1 | 1 | 1 | 12 |
| Mombasa | 5 | 2 | 2 | 5 | 1 | 1 | 3 | 1 | 3 | 2 | 25 |
| Nairobi | 8 | 3 | | 13 | 1 | 4 | 6 | 3 | 4 | 2 | 44 |
| Nyeri | 2 | 1 | 1 | 3 | | 2 | 4 | | 1 | 4 | 18 |
| Siaya | 2 | 1 | 1 | 2 | | 1 | 2 | 1 | 1 | 1 | 12 |
| Vihiga | 2 | 1 | 1 | 3 | | 1 | 2 | 1 | 1 | 1 | 12 |
| Grand Total | **44** | **22** | **17** | **68** | **3** | **25** | **40** | **1** | **26** | **23** | **279** |

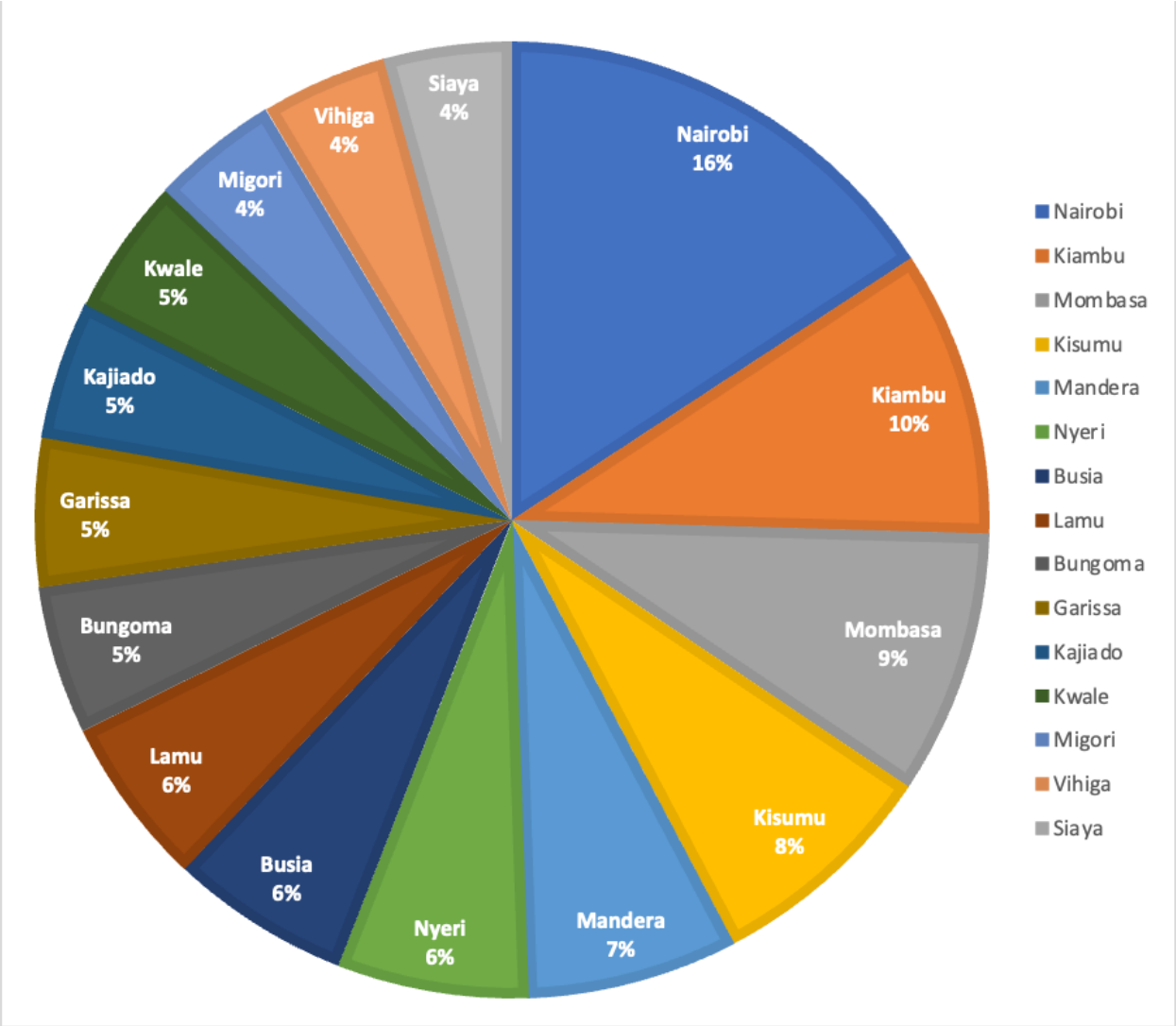


**Figure 3:** Sample distribution by therapeutic indication

### 4.2 Sampling sites (healthcare facilities/ pharmaceutical outlets)

The samples were collected from one-hundred and forty two (142) private facilities, Fourteen (14) public facilities and two (2) Faith Based Organizations (FBOs) spread across fifteen (15) counties.

The following were the number of samples collected from the selected counties

| COUNTY | AMXT | AMXC | CTZT | CPFT | DXBI | ELPT | LVGT | LSTT | MLC | MTZT | SYGN | OMZT | PCTT | PCTS | TLD | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Bungoma** | 1 | 2 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | **14** |
| **Busia** | 1 | 1 | 2 | 2 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | **17** |
| **Garissa** | 2 | 1 | 1 | 1 | | 1 | 1 | 2 | | 1 | 1 | 1 | 1 | 1 | | **14** |
| **Kajiado** | | 1 | 2 | 1 | | 1 | 1 | 1 | | 1 | 1 | 2 | 1 | 1 | | **13** |
| **Kiambu** | 2 | 1 | 3 | 2 | | 2 | 3 | 2 | 1 | 1 | 4 | 2 | 2 | 1 | 1 | **27** |
| **Kisii** | | 1 | | | | | | | | | | | | | | **1** |
| **Kisumu** | 1 | 2 | 1 | 2 | 1 | 1 | 1 | | 2 | 2 | 1 | 2 | 2 | 3 | 1 | **22** |
| **Kwale** | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | **13** |
| **Lamu** | 1 | 3 | 2 | 2 | | 2 | | 1 | 1 | | 1 | 2 | 1 | | | **16** |
| **Mandera** | 2 | 2 | 2 | 3 | | 1 | 1 | 1 | | 3 | 1 | 1 | 2 | 1 | | **20** |
| **Migori** | | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | **12** |
| **Mombasa** | 1 | 1 | 1 | 3 | 1 | 2 | 3 | 1 | 1 | 2 | 1 | 2 | 3 | 2 | 1 | **25** |
| **Nairobi** | 2 | 1 | 4 | 3 | 1 | 3 | 3 | 3 | 1 | 6 | 2 | 3 | 4 | 4 | 3 | **43** |
| **Nyeri** | 1 | 1 | 2 | 1 | | 2 | 1 | 2 | | 1 | 4 | 1 | 1 | 1 | | **18** |
| **Siaya** | | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | **12** |
| **Vihiga** | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | | **12** |
| **Grand Total** | **16** | **21** | **25** | **25** | **3** | **21** | **20** | **19** | **7** | **23** | **22** | **22** | **24** | **20** | **11** | **279** |

**Table 6:** Number of samples collected from the selected counties

*AMXC = Amoxicillin capsules, AMXT = Amoxicillin tablets CPFT = Ciprofloxacin tablets, CTZT = Cetirizine tablets, DXBI = Doxorubicin Injection, ELPT = Enalapril Tablets, LSTT = Losartan tablets, LVGT = Levonorgestrel tablets, OMZC = Omeprazole capsules, PCTS = Paracetamol Suspension, PCTT = Paracetamol tablets*

## 4.3 Samples submitted for compendial testing

A total of seventy-one samples were submitted the NQCL for compendial testing. The table 6 and figure 4 below shows distribution of samples disaggregated by county; that were submitted for compendial testing.

**Table 7:** Secondary sampling matrix

| COUNTY | AMXC | AMXT | CPFT | CTZT | DXBI | ELPT | LSTT | LVGT | MLC | OMZC | PCTS | PCTT | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bungoma | | | 1 | 1 | | | 1 | | | | | | **3** |
| Busia | 1 | | | 2 | | 1 | 1 | | 1 | 1 | | 1 | **8** |
| Garissa | | 1 | | | | 1 | 2 | | | | | | **4** |
| Kajiado | | | 1 | | | | | | | | 1 | | **2** |
| Kiambu | | | 1 | | | 1 | | 1 | 1 | | | 1 | **5** |
| Kisumu | 1 | 1 | | | 1 | | | | 1 | | 1 | | **5** |
| Kwale | 1 | | | | | | 1 | 1 | | | | | **3** |
| Lamu | 1 | | | 1 | | 1 | | | 1 | 1 | | 1 | **6** |
| Mandera | 1 | 1 | | | | | | | | 1 | 1 | 1 | **5** |
| Migori | | | 1 | | | | | | | | | | **1** |
| Mombasa | 1 | | | | 1 | 1 | | | 1 | 1 | 2 | 1 | **8** |
| Nairobi | | | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | | **11** |
| Nyeri | | | | | | 1 | 2 | 1 | | | | | **4** |
| Siaya | | | | 1 | | 1 | | | | 1 | 1 | 1 | **5** |
| Vihiga | | | | | | | | | | | 1 | | **1** |
| **Grand Total** | **6** | **3** | **5** | **7** | **3** | **8** | **8** | **4** | **6** | **6** | **9** | **6** | **71** |

*AMXC = Amoxicillin capsules, AMXT = Amoxicillin tablets CPFT = Ciprofloxacin tablets, CTZT = Cetirizine tablets, DXBI = Doxorubicin Injection, ELPT = Enalapril Tablets, LSTT = Losartan tablets, LVGT = Levonorgestrel tablets, OMZC = Omeprazole capsules, PCTS = Paracetamol Suspension, PCTT = Paracetamol tablet*

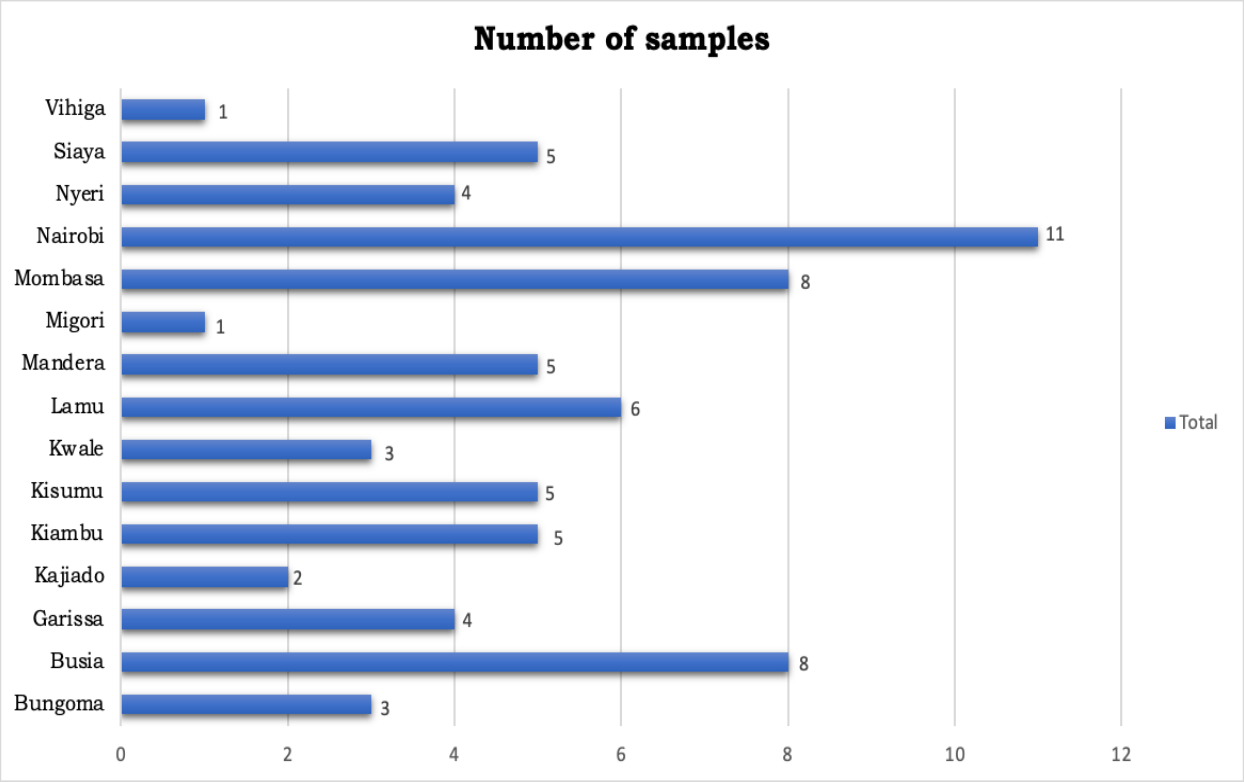


**Figure 4:** Graph on distribution of secondary samples disaggregated by county

## 4.4 Laboratory Analysis Results

### 4.4.1 Field screening using MiniLab technique

Disintegration tests, and Thin Layer Chromatography (TLC) tests were conducted for 171 samples in 3 MiniLabs (Kisumu, Eldoret and Mombasa).

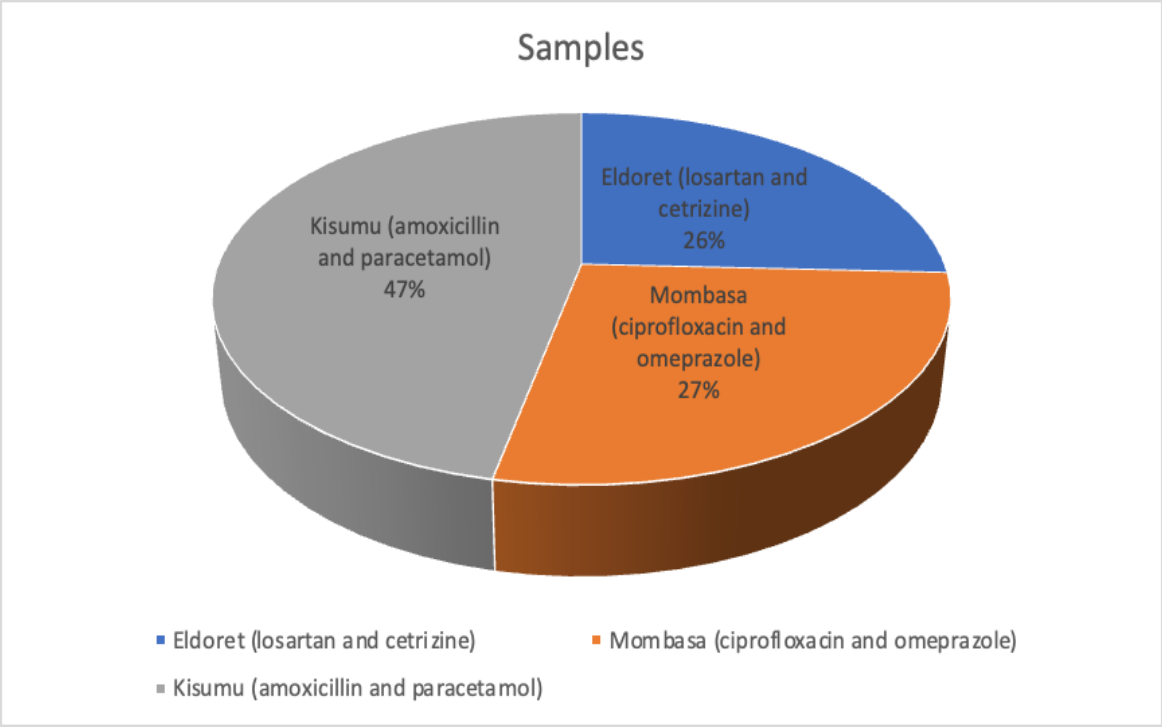


**Figure 5:** Sample distribution by field screening using MiniLab technique

### 4.4.2 Verification using MiniLab technique

Five (5) samples were subjected for verification of the MiniLab results at the Pharmacy and Poisons Board Quality Control Laboratory.

**Table 8:** Samples subjected to verification using MiniLab technique in the PPB-QC Lab

| Serial No. | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient(s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Name and Location of Verification / Confirmatory Lab | Conclusion2 |
|---|---|---|---|---|---|---|---|---|---|
| 1 | KIA/OMZC/04.07.2023/036 | OM | Omeprazole | Capsules | 20mg | Laboratory & Allied Ltd | 83461 | PPB-QC Lab | Pass |
| 2 | BUS/OMZC/01.07.2023/027 | Omeflux | Omeprazole | Capsules | 20mg | Biodeal Laboratories Ltd | 423024 | PPB-QC Lab | Pass |
| 3 | KAJ/OMZC/03.07.2023/049 | OMIS-20 | Omeprazole | Capsules | 20mg | National Pharmacy | B23022 | PPB-QC Lab | Pass |
| 4 | MSA/OMZC/30.06.2023/026 | Ocid | Omeprazole | Capsules | 20mg | Cadila Healthcare Ltd | G300138 | PPB-QC Lab | Pass |
| 5 | LAM/OMZC/04.07.2023/015 | Dawaprazole | Omeprazole | Capsules | 20mg | Dawa Ltd | 2E+06 | PPB-QC Lab | Pass |

### 4.4.3 Summary of the MiniLab results

A total of 171 samples were subjected to field screening using MiniLab technique and 5 samples were subjected to verification using MiniLab technique.

**Table 9:** Summary of the MiniLab results

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient(s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 1 | NYE/LSTT/29.06.2023/002 | Carditan | Losartan | Tablets | 50mg | Cosmos Limited | 220467 | Pass |
| 2 | NYE/CTZT/29.06.2023/005 | RINACET | Cetirizine | Tablets | 10mg | Dawa Limited | 7879/8 | Pass |
| 3 | NYE/CTZT/29.06.2023/009 | Cetirizine | Cetirizine | Tablets | 10mg | Fredun Pharmaceuticals Ltd | ADO320 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 4 | NYE/LSTT/30.06.2023/015 | Losangio-50 | Losartan | Tablets | 50mg | Stallion laboratories limited | E-43 | Pass |
| 5 | KIA/CTZT/03.07.2023/020 | RINACET | Cetirizine | Tablets | 10mg | Dawa Limited | 2211092 | Pass |
| 6 | KIA/LSTT/03.07.2023/024 | Losartas-50 | Losartan | Tablets | 50mg | Intas Pharmaceuticals Ltd | D2200792 | Pass |
| 7 | KIA/CTZT/03.07.2023/026 | Rhizin | Cetirizine | Tablets | 10mg | Ravian Life science Pvt. Ltd | EKERH2003 | Pass |
| 8 | KIA/LSTT/03.07.2023/031 | Carditan | Losartan | Tablets | 50mg | Cosmos Limited | 220198 | Pass |
| 9 | KIA/CTZT/04.07.2023/035 | Altrizine | Cetirizine | Tablets | 10mg | Universal Corporation Ltd. | 5808882 | Pass |
| 10 | GAR/CTZT/30.06.2023/005 | Rhizin | Cetirizine | Tablets | 10mg | Ravian Life Science Pvt.Ltd | EKERH2001 | Pass |
| 11 | GAR/LSTT/01.07.2023/010 | Xartan | Losartan | Tablets | 50mg | Innova Captab Ltd | 17312004 | Pass |
| 12 | GAR/LSTT/01.07.2023/013 | Losartas-50 | Losartan | Tablets | 50mg | Intas Pharmaceuticals Ltd | D2201681 | Pass |
| 13 | MAN/CTZT/04.07.2023/026 | Allerta | Cetirizine | Tablets | 10mg | centurion laboratories pvt ltd | a-48008 | Pass |
| 14 | MAN/CTZT/05.07.2023/031 | Cetrimed | Cetirizine | Tablets | 10mg | Medico Remedies Ltd | CTR203 | Pass |
| 14 | MAN/LSTT/05.07.2023/032 | Losartas-50 | Losartan | Tablets | 50mg | Intas Pharmaceuticals Ltd | D2201681 | Pass |
| 16 | VIH/LSTT/30.06.2023/006 | Carditan | Losartan | Tablets | 50mg | Cosmos Ltd | 220467 | Pass |
| 17 | VIH/CTZT/30.06.2023/010 | Kenzine - 10 | Cetirizine | Tablets | 10mg | Nestor Pharmaceuticals Ltd | (10) NZtZ-06 | Pass |
| 18 | BUS/CTZT/01.07.2023/019 | Cetriz-10 | Cetirizine | Tablets | 10mg | Lab & Allied | 82815 | Pass |
| 19 | BUS/LSTT/01.07.2023/022 | Nusar - 50 | Losartan | Tablets | 50mg | Emcure Pharmaceuticals Ltd | E16S122001 | Pass |
| 20 | BUS/CTZT/01.07.2023/023 | Zycet | Cetirizine | Tablets | 10mg | Biopharma Ltd | BPL 933 | Pass |
| 21 | BUN/CTZT/02.07.2023/034 | Cachcet | Cetirizine | Tablets | 10mg | Cachet Pharmaceuticals Pvt. Ltd | CCT220330E | Pass |
| 22 | BUN/LSTT/02.07.2023/035 | Losatan | Losartan | Tablets | 50mg | Lab & Allied | 80580 | Pass |
| 23 | KAJ/CTZT/03.07.2023/047 | CACHCET | Cetirizine | Tablets | 10mg | Cachet Pharmaceuticals PVT LTD | CCT220226E | Pass |
| 24 | KAJ/CTZT/03.07.2023/052 | Zyncet | Cetirizine | Tablets | 10mg | Unichem Laboratories Limited | BZN-22027 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 25 | KAJ/LSTT/03.07.2023/055 | Losartas-50 | Losartan | Tablets | 50mg | Intas Pharmaceutical Limited | D2202008 | Pass |
| 26 | KWA/LSTT/29.06.2023/002 | Angilock 50 | Losartan | Tablets | 50mg | Square Pharmaceuticals Ltd | 2J00861 | Pass |
| 27 | KWA/CTZT/29.06.2023/004 | Cachet | Cetirizine | Tablets | 10mg | Cachet Pharmaceuticals Ltd | CCT22005E | Pass |
| 28 | MSA/LSTT/30.06.2023/018 | Losartas-50 | Losartan | Tablets | 50mg | Intas Pharmaceuticals Ltd | D2201044 | Pass |
| 29 | MSA/CTZT/30.06.2023/025 | Galchet | Cetirizine | Tablets | 10mg | Fredun Pharmaceuticals | AD0320 | |
| 30 | LAM/CTZT/04.07.2023/006 | Cetriz-10 | Cetirizine | Tablets | 10mg | Lab and Allied | 80657 | Pass |
| 31 | LAM/LSTT/04.07.2023/008 | Carditan | Losartan | Tablets | 50mg | Cosmos Limited | 220468 | Pass |
| 32 | LAM/CTZT/04.07.2023/011 | Zycet | Cetirizine | Tablets | 10mg | Biopharma ltd | BPL952 | Pass |
| 33 | KIS/CTZT/01.07.2023/019 | Zycet | Cetirizine | Tablets | 10mg | Biopharma Ltd | BPL919 | Pass |
| 34 | SIA/CTZT/02.07.2023/025 | RIZEXIN | Cetirizine | Tablets | 10mg | Comet Healthcare Limited | 30624 | Pass |
| 35 | SIA/LSTT/02.07.2023/028 | LOSATAN | Losartan | Tablets | 50mg | Laboratory and Allied Ltd | 82528 | Pass |
| 36 | MIG/LSTT/04.07.2023/039 | Carditan | Losartan | Tablets | 50mg | Cosmos Limited | 211944 | Pass |
| 37 | MIG/CTZT/04.07.2023/045 | Cetriz - 10 | Cetirizine | Tablets | 10mg | Laboratory and Allied Ltd | 82814 | Pass |
| 38 | NAI/CTZT/28.06.2023/005 | Zyncet | Cetirizine | Tablets | 10 | Unichem Laboratories Ltd. | BZN22027 | Pass |
| 39 | NAI/CTZT/28.06.2023/006 | Galcet | Cetirizine | Tablets | 10 | Fedun pharmaceuticals ltd | AD0320 | Pass |
| 40 | NAI/LSTT/28.06.2023/015 | Carditan | Losartan | Tablets | 50 | Cosmol Ltd | 220467 | Pass |
| 41 | NAI/LSTT/28.06.2023/016 | Presartan | Losartan | Tablets | 50 | IPCA labaratories | BSC 422002 | Pass |
| 42 | NAI/CTZT/28.06.2023/024 | Zycet | Cetirizine | Tablets | 10 | biophama Ltd | BPL938 | Pass |
| 43 | NAI/CTZT/28.06.2023/025 | Rezexine | Cetirizine | Tablets | 10 | Comet Heathcare Ltd | 30326 | Pass |
| 44 | NAI/LSTT/28.06.2023/026 | Losatan | Losartan | Tablets | 50 | labaratory & Allied Ltd | 81637 | |
| 45 | NYE/CPFT/29.06.2023/004 | Ciflo | Ciprofloxacin | Tablets | 500mg | Elys Chemicals limited | 3B43 | Pass |
| 46 | NYE/OMZC/30.06.2023/011 | OMIS-20 | Omeprazole | Capsules | 20mg | Brussels Laboratories Pvt. Ltd | C3C077 | Pass |
| 47 | KIA/CPFT/03.07.2023/018 | CIPEX-500 | Ciprofloxacin | Tablets | 500mg | Medico Remedies Limited | CIF306 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 48 | KIA/OMZC/03.07.2023/022 | OMIS-20 | Omeprazole | Capsules | 20mg | Brussels Laboratories Pvt. Ltd | B023023 | Pass |
| 49 | KIA/CPFT/03.07.2023/028 | Ciproglax | Ciprofloxacin | Tablets | 500mg | Fredun Pharmaceuticals Ltd | CB0094 | Pass |
| 50 | GAR/OMZC/30.06.2023/006 | OMIS-20 | Omeprazole | Capsules | 20mg | Brussels Laboratories PVT,ltd | C3C079 | Pass |
| 51 | GAR/CPFT/01.07.2023/012 | Cipex-500 | Ciprofloxacin | Tablets | 500mg | Medico Remedies Ltd | CIF302 | Pass |
| 52 | MAN/CPFT/04.07.2023/017 | CIPROKEN | Ciprofloxacin | Tablets | 500MG | Square Pharmaceuticals Ltd | 3 C01453 | Pass |
| 53 | MAN/CPFT/04.07.2023/027 | Guciprox | Ciprofloxacin | Tablets | 500mg | Guilin Pharmaceutical co.ltd | HB23040 | Pass |
| 54 | MAN/CPFT/04.07.2023/028 | C-Cipro | Ciprofloxacin | Tablets | 500mg | Innova Captab Ltd | G113E2008 | Pass |
| 55 | MAN/OMZC/05.07.2023/034 | OMIS-20 | Omeprazole | Capsules | 20mg | Brussels Laboratories PVT,ltd | B 23049 | Pass |
| 56 | VIH/CPFT/30.06.2023/009 | Ciprolab - 500 | Ciprofloxacin | Tablets | 500mg | Lab & Allied | 83579 | Pass |
| 57 | BUS/CPFT/01.07.2023/020 | Ciprodin | Ciprofloxacin | Tablets | 500mg | Dinlas Pharma EPZ Ltd | 220457 | Pass |
| 58 | BUS/CPFT/01.07.2023/021 | Cipex - 500 | Ciprofloxacin | Tablets | 500mg | Medico Remedies Ltd | CIF306 | Pass |
| 59 | BUN/CPFT/02.07.2023/038 | Comcip-500 | Ciprofloxacin | Tablets | 500mg | Comet Healthcare Ltd | 30412 | Pass |
| 60 | BUN/OMZC/02.07.2023/041 | OCID | Omeprazole | Capsules | 20mg | Cadilla Healthcare Ltd | G202731 | Pass |
| 61 | KAJ/OMZC/03.07.2023/046 | OCID | Omeprazole | Capsules | 20mg | Kandaim industrial estate | G202731 | Pass |
| 62 | KAJ/CPFT/03.07.2023/048 | GUCIPROX | Ciprofloxacin | Tablets | 500mg | Guilin Pharmaceuticals Co. Ltd | HB230403 | Pass |
| 63 | KAJ/OMZC/03.07.2023/049 | OMIS-20 | Omeprazole | Capsules | 20mg | National Pharmacy | B23022 | Pass |
| 64 | KWA/OMZC/29.06.2023/007 | Omicap 20 | Omeprazole | Capsules | 20mg | Micro Labs Ltd | OMWH0045 | Pass |
| 65 | KWA/CPFT/29.06.2023/013 | Cipex-500 | Ciprofloxacin | Tablets | 500mg | Medico Remedies Ltd | CIF302 | Pass |
| 66 | MSA/CPFT/30.06.2023/015 | Guciprox | Ciprofloxacin | Tablets | 500mg | Guilin Pharmaceuticals Co.Ltd | HB220603 | Pass |
| 67 | MSA/CPFT/30.06.2023/021 | Ciprodon | Ciprofloxacin | Tablets | 500mg | Dinlas Pharma EPZ Ltd | 220447 | Pass |
| 68 | MSA/CPFT/01.07.2023/035 | Omacip-500 | Ciprofloxacin | Tablets | 500mg | National Pharmaceuticals Company Ltd | 2021334 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 69 | MSA/OMZC/01.07.2023/037 | Ocid | Omeprazole | Capsules | 20mg | Cadila Healthcare Ltd | G202731 | Pass |
| 70 | LAM/OMZC/04.07.2023/002 | Omecos | Omeprazole | Capsules | 20mg | Cosmos Limited | 220909 | Pass |
| 71 | LAM/CPFT/04.07.2023/007 | Ciprocos | Ciprofloxacin | Tablets | 500mg | Cosmos Limited | 220684 | Pass |
| 72 | LAM/CPFT/04.07.2023/016 | Ciprodin | Ciprofloxacin | Tablets | 500mg | Dinlas Pharma | 220457 | Pass |
| 73 | KIS/OMZC/30.06.2023/015 | OMZ-20 | Omeprazole | Capsules | 20mg | Aksharam Pharama Private Ltd | 505K2201 | Pass |
| 74 | KIS/OMZC/01.07.2023/018 | Omis-20 | Omeprazole | Capsules | 20mg | Brussels Laboratories Pvt Ltd | B23020 | Pass |
| 75 | KIS/CPFT/01.07.2023/020 | Guciprox | Ciprofloxacin | Tablets | 500mg | Guilin Pharmaceuticals Ltd | HB220603 | Pass |
| 76 | KIS/CPFT/01.07.2023/022 | Cipex 500 | Ciprofloxacin | Tablets | 500mg | Medico Remedies Ltd | CIF303 | Pass |
| 77 | SIA/OMZC/03.07.2023/033 | DAWAPRAZ | Omeprazole | Capsules | 20mg | Dawa Ltd | 2301152 | Pass |
| 78 | MIG/CPFT/04.07/2023/040 | Ciprodeal | Ciprofloxacin | Tablets | 500mg | Biodeal Laboratories Ltd | 1022012 | Pass |
| 79 | MIG/OMZC/04.07.2023/046 | Omeflux | Omeprazole | Capsules | 20mg | Biodeal Laboratories Ltd | 423022 | Pass |
| 80 | NAI/OMZC/28.06.2023/003 | OMS-20 | Omeprazole | Capsules | 20 | National pharmacy ltd | B23020 | Pass |
| 81 | NAI/OMZC/28.06.2023/004 | OMICAP - 20 | Omeprazole | Capsules | 20 | MICRO LABS LTD | OMWH0045 | Pass |
| 82 | NAI/CPFT/28.06.2023/007 | C-CIPRO | Ciprofloxacin | Tablets | 500 | Innova captab limited | G113E2007 | Pass |
| 83 | NAI/CPFT/28.06.2023/008 | Shalcip | Ciprofloxacin | Tablets | 500 | shalina labaratoriespvt ltd | 1371686 | Pass |
| 84 | NAI/CPFT/28.06.2023/009 | Ciprointa | Ciprofloxacin | Tablets | 500 | Intas phamaceuticals Ltd | D2203097 | Pass |
| 85 | NAI/OMZC/28.06.2023/034 | onpraz | Omeprazole | Capsules | 20 | crown healthcare | IC641010 | Pass |
| 86 | NYE/AMXC/29.06.2023/001 | Amoximed | Amoxicillin | Capsules | 500mg | CSPC Zhongnun Pharma | 706230340 | Pass |
| 87 | NYE/PCTS/29.06.2023/003 | Micromol | Paracetamol | Suspension | 120mg/5ml | Zain Pharma Limited | 2L23199 | Pass |
| 88 | NYE/PCTT/29.06.2023/006 | Simdol | Paracetamol | Tablets | 500mg | Africure Pharmaceuticals Pvt Limited | 912 | Pass |
| 89 | NYE/AMXT/29.06.2023/008 | Kemoxyl DT 250 | Amoxicillin | Dispersible tablets | 250mg | Laboratory & Allied Ltd | 82756 | Pass |
| 90 | KIA/AMXT/03.07.2023/019 | MOXACIL - 500 | Amoxicillin | Tablets | 500mg | Dawa Limited | 2302042 | Pass |
| 91 | KIA/AMXT/03.07.2023/027 | Kemoxyl DT 250 | Amoxicillin | Tablets | 250mg | Laboratory & Allied Ltd | 82758 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 92 | KIA/PCTT/03.07.2023/029 | Regamol | Paracetamol | Tablets | 500mg | Bal Pharma Limited | PET515 | Pass |
| 93 | KIA/AMXT/04.07.2023/034 | Kemoxyl DT 250 | Amoxicillin | Tablets | 250mg | Laboratory & Allied Ltd | 82755 | Pass |
| 94 | KIA/PCTT/04.07.2023/039 | PARADOL | Paracetamol | Tablets | 500mg | Dinlas Pharma EPZ Ltd. | 220436 | Pass |
| 95 | GAR/PCTS/30.06.2023.001 | Curamol | Paracetamol | Suspension | 120mg/5ml | Dawa Limited | 2303186 | Pass |
| 96 | GAR/AMXT/30.06.2023/002 | Amoximed 250mg Dispersible Tablets | Amoxicillin | Tablets | 250mg | CSPC Zhangnua Pharmaceutical(Shijazhuang) Co.Ltd | 797221209 | Pass |
| 97 | GAR/AMXT/30.06.2023/004 | Amoxicillin 250mg USP | Amoxicillin | Tablets | 250mg | Reyoung Pharmaceutical Co.Ltd | 223131097 | Pass |
| 98 | GAR/PCTT/30.06.2023/008 | Cetamol | Paracetamol | Tablets | 500mg | Regal Pharmaceuticals Ltd | 230426 | Pass |
| 99 | GAR/AMXC/01,07.2023/011 | Moxilact | Amoxicillin | Capsules | 500mg | Reyoung Pharmaceutical Co.Ltd | 223131247 | Pass |
| 100 | MAN/AMOXC/04.07.2023/015 | Rivamox | Amoxicillin | Capsules | 500mg | Riva Pharma | 220159 | Pass |
| 101 | MAN/AMOXT/04.07.2023/018 | Amoxicillin 250mg | Amoxicillin | Tablets | 250mg | Remedia LTD | 100515 | Pass |
| 102 | MAN/AMOXT/04.07.2023/019 | amoxicillin 250mg | Amoxicillin | Tablets | 250mg | Sandoz GmbH | LL7954 | Pass |
| 103 | MAN/PCTT/04.07.2023/020 | paradol | Paracetamol | Tablets | 500mg | Dinlas Pharma EPZ ltd | 220362 | Pass |
| 104 | MAN/PCTT/04.07.2023/021 | paracetamol 500mg BP | Paracetamol | Tablets | 500mg | Medopharm | MG133 | Pass |
| 105 | MAN/AMXC/04.07.2023/023 | Moximed | Amoxicillin | Capsules | 500mg | Medivet products ltd | P 3151 | Pass |
| 106 | MAN/PCTS/04.07.2023/025 | Micromol | Paracetamol | Suspension | 120mg/5ml | Zain Pharma Ltd | ZL23120 | Pass |
| 107 | VIH/PCTT/29.06.2023/002 | Regamol | Paracetamol | Tablets | 500mg | Bal Pharma Ltd | PET505 | Pass |
| 108 | VIH/AMXT/30.06.2023/005 | Amoximed 250mg Dispersible Tablets | Amoxicillin | Dispersible tablets | 250mg | CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd | 797221115 | Pass |
| 109 | VIH/PCTS/30.06.2023/007 | Paradol | Paracetamol | Suspension | 120mg/5mL | Dinlas Pharma EPZ Ltd | 220456 | Pass |
| 110 | VIH/AMXC/30.06.2023/008 | Amoximed | Amoxicillin | Capsules | 500mg | CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd | 70623339 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 111 | BUS/AMXC/01.07.2023/013 | Caremox - 500 | Amoxicillin | Capsules | 500mg | Sinopharm Weiqida Pharmaceuticals Co., Ltd | 220909 | Pass |
| 112 | BUS/AMXT/01.07.2023/015 | Kemoxyl DT 250 | Amoxicillin | Dispersible tablets | 250mg | Lab & Allied | 82632 | Pass |
| 113 | BUS/PCTT/01.07.2023/017 | Vivamol | Paracetamol | Tablets | 500mg | Viva Healthcare Ltd | 122062 | Pass |
| 114 | BUS/PCTS/01.07.2023/026 | Micromol | Paracetamol | Suspension | 120mg/5mL | Zain Pharman Ltd | ZL23213 | Pass |
| 115 | BUS/PCTT/01.07.2023/028 | Paratal | Paracetamol | Tablets | 500mg | Lab & Allied | 83174 | Pass |
| 116 | BUN/AMXC/02.07.2023/029 | Kemoxyl 500 | Amoxicillin | Capsules | 500mg | Lab & Allied | 83115 | Pass |
| 117 | BUN/PCTT/02.07.2023/031 | Cetamol | Paracetamol | Tablets | 500mg | Regal Pharmaceuticals Ltd | 230817 | Pass |
| 118 | BUN/PCTS/02.07.2023/037 | Curamol | Paracetamol | Suspension | 120mg/5mL | Dawa Ltd | 2302105 | Pass |
| 119 | BUN/AMXC/02.07.2023/039 | Moximed | Amoxicillin | Capsules | 500mg | Medivet Products Ltd | P3274 | Pass |
| 120 | BUN/AMXT/02.07.2023/042 | Kemoxyl DT 250 | Amoxicillin | Tablets | 250mg | Lab & Allied | 82632 | Pass |
| 121 | KAJ/AMXC/03.07.2023/050 | Moxacil-500 | Amoxicillin | Capsules | 500mg | Dawa LTD | 2306033 | Pass |
| 122 | KAJ/PCTS/03.07.2023/054 | Betamol | Paracetamol | Suspension | 120mg | Sphinx Pharmaceuticals LTD | 02388P | Pass |
| 123 | KAJ/PCTT/03.07.2023/056 | Paratal | Paracetamol | Tablets | 500mg | Laboratory and Allied Limited | 82861 | Pass |
| 124 | KWA/AMXC/29.06.2023/003 | Amoximed | Amoxicillin | Capsules | 500mg | CSPC Zhonghuo Pharmaceuticals Co.Ltd | 706230340 | Pass |
| 125 | KWA/PCTT/29.06.2023/005 | Rapidol | Paracetamol | Tablets | 500mg | Medico Remedies Ltd | RAD209 | Pass |
| 126 | KWA/AMXT/29.06.2023/006 | Kemoxyl DT | Amoxicillin | Dispersible tablets | 250mg | Lab and Allied | 83232 | Pass |
| 127 | KWA/PCTS/29.06.2023/009 | Curamol Suspension | Paracetamol | Suspension | 120mg/5ml | Dawa Ltd | 2212023 | Pass |
| 128 | MSA/PCTT/30.06.2023/016 | Paratal | Paracetamol | Tablets | 500mg | Lab and Allied | 82858 | Pass |
| 129 | MSA/AMXC/30.06.2023/027 | Kemoxyl 250 | Amoxicillin | Capsules | 250mg | Lab and Allied | 81567 | Pass |
| 130 | MSA/PCTT/30.06.2023/029 | Cetamol | Paracetamol | Tablets | 500mg | Regal Pharmaceuticals Ltd | 230818 | Pass |
| 131 | MSA/AMXC/30.06.2023/031 | Kemoxyl DT | Amoxicillin | Capsules | 500mg | Lab and Allied | 83115 | Pass |
| 132 | MSA/PCTS/01.07.2023/033 | Toto-mol | Paracetamol | Suspension | 120mg/5ml | Lab and Allied | 2122 | Pass |
| 133 | MSA/PCTT/01.07.2023/036 | Betamol | Paracetamol | Tablets | 500mg | Sphinx Pharmaceuticals Ltd | 01069PT | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 134 | MSA/PCTS/01.07.2023/038 | Jotomol | Paracetamol | Suspension | 120mg/5ml | Benmed Pharmaceuticals Ltd | 723 | Pass |
| 135 | LAM/AMXT/04.07.2023/001 | Kemoxyl DT | Amoxicillin | Dispersible tablets | 250mg | Lab and Allied | 81587 | Pass |
| 136 | LAM/PCTT/04.07.2023/004 | Cetamol | Paracetamol | Tablets | 500mg | Regal Pharmaceuticals Ltd | 221738 | Pass |
| 137 | LAM/AMXC/04.07.2023/005 | Moximed | Amoxicillin | Capsules | 500mg | Medivet Product Ltd | P3188 | Pass |
| 138 | LAM/AMXC/04.07.2023/013 | Kemoxyl 250 | Amoxicillin | Capsules | 250mg | Lab and Allied | 81971 | Pass |
| 139 | LAM/AMXC/04.07.2023/014 | Caremox-500 | Amoxicillin | Capsules | 500mg | Sinopharm weiqida pharmaceutical co;ltd | 221044 | Pass |
| 140 | KIS/PCTS/29.06.2023/003 | Betamol | Paracetamol | Suspension | 120mg/5ml | Sphinx Pharmaceuticals Ltd | 02366P | Pass |
| 141 | KIS/PCTS/29.06.2023/004 | Junior Sonadol | Paracetamol | Suspension | 120mg/5ml | Zain Pharma Ltd | OL 23002 | Pass |
| 142 | KIS/PCTS/29.06.2023/005 | Paradol oral solution | Paracetamol | Suspension | 120mg/5ml | Dinlas Pharma EPZ Ltd | 220419 | Pass |
| 143 | KIS/PCTT/29.06.2023/007 | XYKAA EXTEND 1000 | Paracetamol | Tablets | 1000mg | Troikaa Pharmaceuticals Ltd | X37607 | Pass |
| 144 | KIS/AMXC/29.06.2023/008 | Kemoxyl 250 | Amoxicillin | Capsules | 250mg | Laboratory and Allied Ltd | 81969 | Pass |
| 145 | KIS/AMXC/30.06.2023/010 | Moxacil | Amoxicillin | Capsules | 250mg | Dawa Ltd | 2205238 | Pass |
| 146 | KS/PCTT/30.06.2023/011 | Cetamol | Paracetamol | Tablets | 500mg | Regal Pharmaceuticals Ltd | 230411 | Pass |
| 147 | KIS/AMXT/30.06.2023/012 | Kemoxyl 250 | Amoxicillin | Tablets | 250mg | Laboratory and Allied Ltd | 83200 | Pass |
| 148 | SIA/PCTT/02.07.2023/024 | SIMDOL | Paracetamol | Tablets | 500mg | Africure Pharmaceuticals (India) Private Limited | 3810 | Pass |
| 149 | SIA/PCTS/02.07.2023/026 | PAMOL | Paracetamol | Suspension | 120mg/5ml | Comet Healthcare Limited | 230527 | Pass |
| 150 | SIA/AMXC/03.07.2023/032 | AMOXIMED | Amoxicillin | Capsules | 500mg | CSPC Zhongnuo Pharmaceuticals (Shijiangzhuang) Co. Ltd | 706230339 | Pass |
| 151 | MIG/PCTS/04.07.2023/035 | Micromol | Paracetamol | Suspension | 120mg/5ml | Zain Pharma Ltd | LMI23006 | Pass |
| 152 | MIG/PCTT/04.07.2023/038 | Paratal | Paracetamol | Tablets | 500mg | Laboratory and Allied Ltd | 83503 | Pass |
| 153 | MIG/AMXC/04.07.2023/043 | Omacillin | Amoxicillin | Capsules | 250mg | National Pharmaceutical Industries Co. (SAOG) | O322011 | Pass |

| S/N | Sample Code No. | Medicine Brand Name | Active Pharmaceutical Ingredient (s) (API) | Dosage Form | Dosage Strength | Name of Manufacturer | Batch or Lot Number | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 154 | NAI/AMXC/28.06.2023/001 | MOXACIL - 500 | Amoxicillin | Capsules | 500 | DAWA PHARMACEUTICALS LTD | 2303067 | Pass |
| 155 | NAI/AMXC/28.06.2023/002 | OMACILLIN | Amoxicillin | Capsules | 500 | National pharmaceuticals Industries. Co | 322009 | Pass |
| 156 | NAI/PCTT/28.06.2023/011 | paratol | Paracetamol | Tablets | 500 | Labaratory and Allied Ltd | 82860 | Pass |
| 157 | NAI/PCTT/28.06.2023/012 | cetamol | Paracetamol | Tablets | 500 | Regal pvt Ltd | 230824 | Pass |
| 158 | NAI/PCTC/28.06.2023/021 | betamol | Paracetamol | oral suspension | 120 | sphinx pharmaceuticals Ltd | 02373P | Pass |
| 159 | NAI/PCTC/28.06.2023/022 | Trumol | Paracetamol | oral suspension | 120 | Truphecruna manufactory Ltd | 123036 | Pass |
| 160 | NAI/PCTT/28.06.2023/027 | Elymol | Paracetamol | Tablets | 500 | Elys chemical Industries ltd | 3C70 | Pass |
| 161 | NAI/PCTT/28.06.2023/028 | betamol | Paracetamol | Tablets | 500 | Shpinx pharmaceuticals Ltd | 01115PT | Pass |
| 162 | NAI/PCTS/28.06.2023/030 | Micromal | Paracetamol | Suspension | bottle | zain pharm limited | LM123006 | Pass |
| 163 | NAI/PCTS/28.06.2023/031 | Curamol | Paracetamol | Suspension | bottle | dawa limited | 2305066 | Pass |
| 164 | NAI/AMXT/28.06.2023/032 | Kemoxyl DT | Amoxicillin | Dispersible tablets | 250 | labaratory & Allied Ltd | 83281 | Pass |
| 165 | NAI/AMXT/28.06.2023/033 | | Amoxicillin | Dispersible tablets | 250 | CSPC Zhounghu phamaceutical co ltd | 797221118 | Pass |

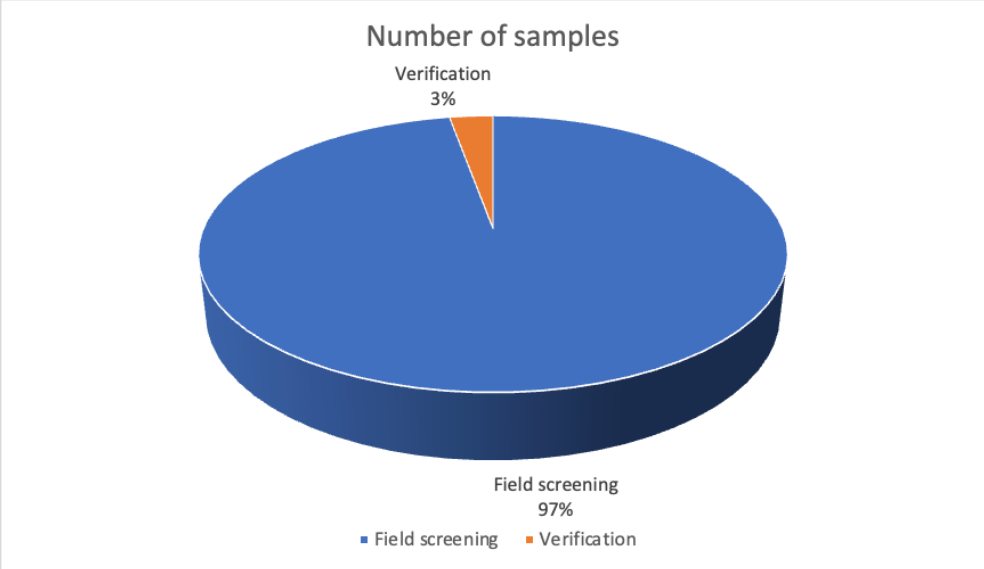

**Figure 6:** Samples that were tested using MiniLab technique

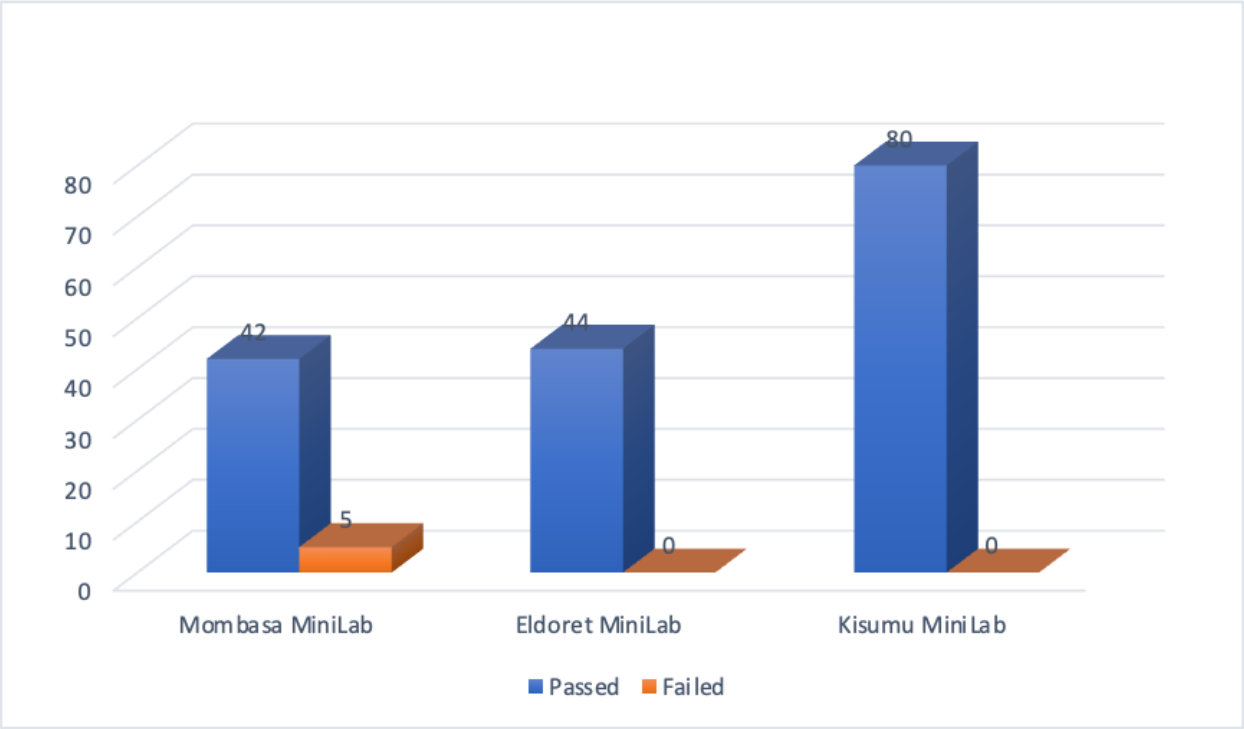


**Figure 7:** Results of field screening using MiniLab technique

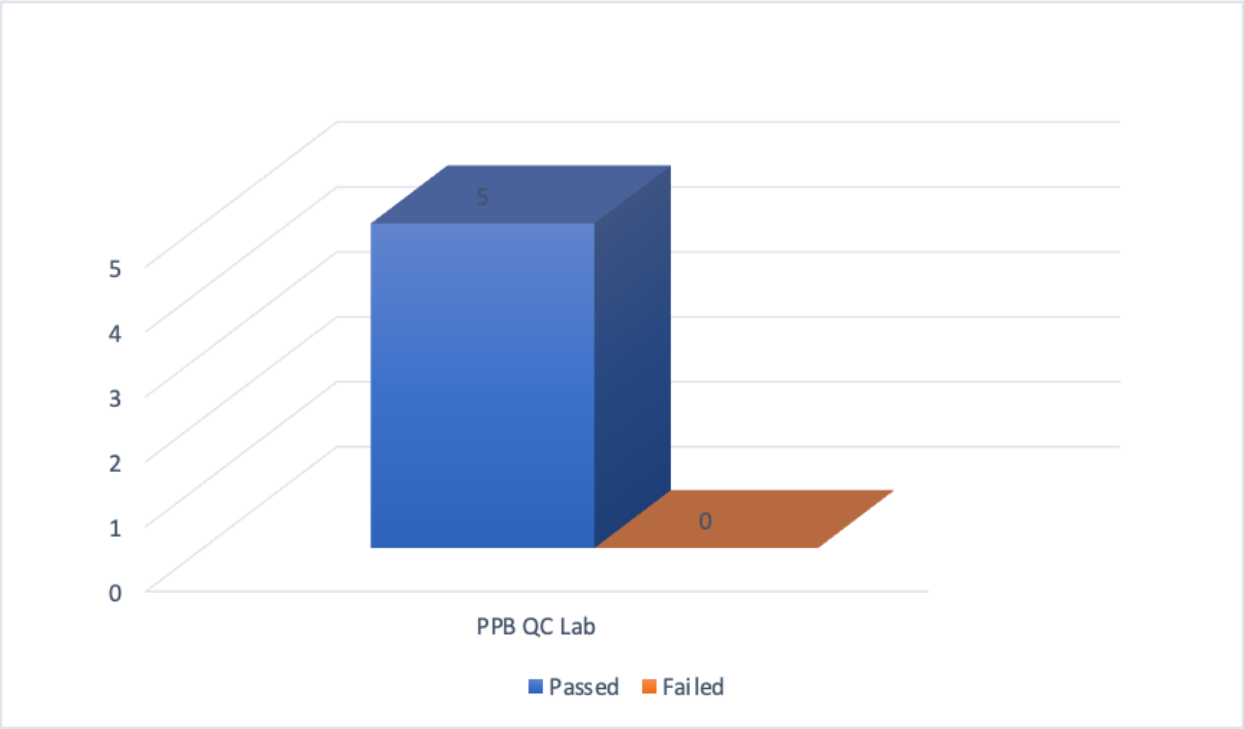


**Figure 8:** Results of verification screening using MiniLab technique

### 4.4.4 Summary of compendial results

The table and figure below summarizes the compliance status of the analyzed health product samples

**Table 10:** Summary of compliance status of health products

| ANALYTICAL TESTS PERFORMED | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Uniformity of weight** | | **Dissolution** | | **Assay** | | **Microbial load** | | **Acidity/ Alkalinity** | | **Bacterial Endotoxins** | | **Quantity of lubricant** | | **Dimensions** | | **Burst volume and pressure** | | **Freedom from holes** | |
| Compliance | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply | Complies | Does not comply |
| Losartan Tablets | 8 | 0 | 8 | 0 | 8 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Omeprazole Capsules | 6 | 0 | 6 | 0 | 6 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Amoxicillin Capsules | 6 | 0 | 6 | 0 | 6 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Amoxicillin DT | 3 | 0 | 3 | 0 | 3 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Cetirizine Tablets | 7 | 0 | 7 | 0 | 7 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Enalapril Tablets | 9 | 0 | 9 | 0 | 8 | 1 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Paracetamol Tablets | 6 | 0 | 6 | 0 | 6 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Ciprofloxacin Tablets | 5 | 0 | 5 | 0 | 5 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Levonorgestrel tablets | 4 | 0 | 4 | 0 | 4 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Paracetamol suspension | N/A | 0 | N/A | 0 | 9 | 0 | 9 | 0 | 9 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Doxorubicin Injection | N/A | 0 | N/A | 0 | 3 | 0 | N/A | N/A | 3 | 0 | 3 | 0 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Male Latex Condoms | N/A | 0 | N/A | 0 | N/A | 0 | N/A | N/A | N/A | N/A | N/A | N/A | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 |
| **Total** | **54** | **0** | **54** | **0** | **66** | **1** | **9** | **0** | **12** | **0** | **3** | **0** | **6** | **0** | **0** | **0** | **6** | **0** | **0** | **0** |
| **% Compliance** | **100%** | **0** | **100 %** | **0** | **98.51 %** | **1.49 %** | **100%** | **0** | **100%** | **0** | **100 %** | **0** | **100 %** | **0** | **100 %** | **0** | **100 %** | **0** | **100 %** | **0** |

### 4.4.4.1 Paracetamol Suspension

**Table 11:** Analysis Results for Paracetamol suspension

| | Unique sample code | Brand Name | Name Of Manufacturer | Batch Number | NDQA 202308- | CAN/2023-24/ | Microbial load | Acidity/ Alkalinity | Assay | Compliance |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | KIS/PCTS/29.06.2023/004 | Junior Sonadol Suspension | Zain Pharma Ltd | OL23002 | 041 | 097 | < 10 CFU/mL | 5.4 | 93.90% | Complies |
| 2 | SIA/PCTS/02.07,2023/026 | Pamol Suspension | Comet Healthcare Ltd | 230527 | 040 | 098 | < 10 CFU/mL | 58 | 95.50% | Complies |
| 3 | NAI/PCTS/28.06.2023/022 | Trumol Suspension | Trupharma Manufacturing Ltd | 123036 | 039 | 099 | < 10 CFU/mL | 5.5 | 91.70% | Complies |
| 4 | NAI/PCTS/28.06.2023/031 | Curamol Suspension | Dawa Limited | 2305066 | 037 | 101 | < 10 CFU/mL | 5.3 | 98.10% | Complies |
| 5 | MSA/PCTS/01.07.2023/033 | Toto-Mol Suspension | Laboratory And Allied Ltd | 82122 | 045 | 093 | < 10 CFU/mL | 5 | 93.40% | Complies |
| 6 | MAN/PCTS/04.07.2023/25 | Micromol Oral Suspension | Zain Pharma Ltd | ZL23120 | 044 | 094 | < 10 CFU/mL | 4.9 | 99.70% | Complies |
| 7 | KAJ/PCTS/03.07.203/054 | Betamol Suspension | Sphinx Pharmaceutical Ltd | 02388P | 043 | 095 | < 10 CFU/mL | 5.4 | 96.50% | Complies |

| | Unique sample code | Brand Name | Name Of Manufacturer | Batch Number | NDQA 202308- | CAN/2023-24/ | Microbial load | Acidity/ Alkalinity | Assay | Compliance |
|---|---|---|---|---|---|---|---|---|---|---|
| 8 | VIH/PCTS/30.06.2023/007 | Paradol Oral Solution Bp | Dinlas Pharma Epz Ltd | 220456 | 042 | 096 | < 10 CFU/mL | 5.3 | 102.00% | Complies |
| 9 | MSA/PCTS/01.07.2023/038 | Jotonol Suspension | Benmed Pharmaceuticals Ltd | 73 | 038 | 100 | < 10 CFU/mL | 4.7 | 99.30% | Complies |

#### 4.4.4.2 Losartan Tablets

**Table 12:** Analysis Results for Losartan tablets

| | Unique sample code | Brand Name | Name Of Manufacturer | Batch Number | NDQA 202308- | CAN/ 2023 24/ | Uniformity of weight | Dissolution | Assay | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** | NYE/LSTT/29.06.2023/002 | Carditan 50mg | Cosmos Ltd | 220467 | 077 | 129 | None deviates | 99% | 100.30 % | Complies |
| **2** | NAI/LSTT/28.06.2023/016 | Presartan-50 | Ipca Laboratories Ltd | BSC422002 | 075 | 130 | None deviates | 99% | 103.30 % | Complies |
| **3** | NAI/LSTT/28.06.2023/015 | Losangio-50 | Stallion Laboratories Pvt Ltd | E-43 | 076 | 131 | None deviates | 98% | 100% | Complies |
| **4** | GAR/LSTT/01.07.2023/010 | Xartan 50 | Innova Captab Ltd | 17312004 | 071 | 132 | None deviates | 95% | 101.50 % | Complies |

| | Unique sample code | Brand Name | Name Of Manufacturer | Batch Number | NDQA 202308- | CAN/ 2023 24/ | Uniformity of weight | Dissolution | Assay | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|
| **5** | KWA/LSTT/29.06.2023/002 | Angilock 50 | Square Pharmaceuticals Ltd | 2J00861 | 078 | 133 | None deviates | 98% | 102.60 % | Complies |
| **6** | GAR/LSTT/01.07.2023/013 | Losartas-50 | Intas Pharmaceuticals Ltd | D2201681 | 072 | 136 | None deviates | 98% | 98.30% | Complies |
| **7** | BUN/LSTT/02.07.2023/035 | Losatan 5omg | Laboratory And Allied Ltd | 80580 | 074 | 134 | None deviates | 99% | 98% | Complies |
| **8** | BUS/LSTT/01.07.2023/022 | Nusar-50 | Emcure Pharmaceuticals Ltd | E16S122001 | 073 | 134 | None deviates | 99% | 99% | Complies |

### 4.4.4.3 Doxorubicin Injection

**Table 13:** Analysis results for Doxorubicin injection

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Bacterial Endotoxins | Acidity/ Alkalinity | Assay | |
| 1 | KIS/DXBI/30.06.2023/016 | Zuvidox 50 Injection | Zuvius LifeSciences Pvt. Ltd | ZBDRL2203YA | 056 | 179 | 1.3 EU/mg | 6 | 95.60% | Complies |
| **2** | NAI/DXBI/29.06.2023/042 | Doxoruba 50mg/25mg Injection | Getwell Pharmaceuticals | 2GDX11 | 111 | 177 | 1.3 EU/mg | 3.7 | 96.50% | Comples |
| **3** | MSA/DXBI/30.06.2023/020 | Naprodox 50 For Injection | Naprod Life Sciences Pvt. Ltd | NN1472A | 055 | 78 | 1.3 EU/mg | 6 | 95.50% | Complies |

### 4.4.4.4 Omeprazole Capsules

**Table 14:** Analysis Results Omeprazole capsules

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | | | Assay | |
| | | | | | | | | Acid state | | Buffer state | | | |
| | | | | | | | | Average | Range | Average | Range | | |
| 1 | MAN/OMZC/05.07.2023/034 | OMIS-20 Capsules | Brussels Laboratories Pvt Ltd | B23049 | 084 | 157 | None Deviates | 0% | 0% | 103 % | 103-104% | 103.60 % | Complies |
| 2 | LAM/OMZC/04.07.2023/002 | Omecos Delayed-Release Capsules 20mg | Cosmos Limited | 220909 | 083 | 156 | None Deviates | 0% | 0% | 100 % | 100-102% | 100.70 % | Complies |
| 3 | NAI/OMZC/28.06.2023/034 | Onpraz Capsules 20mg | Innova CapTab | IC641010 | 082 | 155 | None Deviates | 0% | 0% | 105 % | 104.7-105.1 % | 102.60 % | Complies |
| 4 | BUS/OMZC/01.07.2023/027 | Omeflux Capsules 20mg | Biodeal Laboratories Limited | 0423024 | 081 | 154 | None Deviates | 0% | 0% | 100 % | 99-100% | 102.90 % | Complies |

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | | | Assay | |
| | | | | | | | | Acid state | | Buffer state | | | |
| | | | | | | | | Average | Range | Average | Range | | |
| 5 | MSA/OMZC/30.06.2023/026 | Ocid 20mg Capsules | Cadila Healthcare Limited | G300138 | 080 | 153 | None Deviates | 0% | 0% | 105 % | 104.7-105.2 % | 102.20 % | Complies |
| 6 | SIA/OMZC/03.07.2023/033 | Dawapraz Capsules 20MG | Dawa Limited | 2301152 | 079 | 152 | None Deviates | 0% | 0% | 104 % | 102-105% | 101.80 % | Complies |

#### 4.4.4.5 Amoxicillin Capsules

**Table 15:** Analysis Results for Amoxicillin capsules

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA20 2308- | CAN/ 2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| | | | | | | | | Average | Range | | |
| **1** | KWA/AMXC/29.06.2023/003 | Amoximed BP 500mgCapsules | CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd | 706230340 | 047 | 119 | None deviates | 94%% | 92-99% | 101% | Complies |

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA20 2308- | CAN/ 2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| | | | | | | | | Average | Range | | |
| **2** | MAN/AMXC /04.07.2023/015 | Rivamox Capsules | Riva Pharma | 220159 | 046 | 120 | None deviates | 91% | 88-94% | 102.7%% | Complies |
| **3** | BUS/AMXC /01.07.2023/013 | Caremox-500 Capsules | Sinopharm Weiqida Pharmaceutical CO., LTD | 220909 | 048 | 121 | None deviates | 95%% | 93-96% | 100.8%% | Complies |
| **4** | LAM/AMXC /04.07.2023/014 | Caremox-500 Capsules | Sinopharm Weiqida Pharmaceutical CO., LTD | 221044 | 049 | 122 | None deviates | 96%% | 94-99% | 98.9%% | Complies |
| **5** | MSA/AMXC /30.06.2023/031 | Kemoxyl 500 Capsules | Laboratory & Allied Ltd | 83115 | 050 | 123 | One deviates 12.4% | 94% | 93-96% | 99.60% | Complies |
| **6** | KIS/AMXC/ 30.06.2023 /010 | Moxacil-250 Capsules | Dawa Limited | 2205238 | 053 | 124 | None deviates | 96% | 94-98% | 97.40% | Complies |

### 4.4.4.6 Amoxicillin Dispersible Tablets

**Table 16:** Analysis Results for Amoxicillin Dispersible Tablets (DT)

| | | | | | | | Test results | Conclusion |
|---|---|---|---|---|---|---|---|---|

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 20230 8- | CAN/2 023-24/ | Uniformity of weight | Dissolution | | Assay | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Average | Range | | |
| **1** | KIS/AMXT /30.06.20 23/012 | Kemoxyl DT 250 tablets | Laboratory andAllied | 83200 | 051 | 184 | None deviates | 87% | 87-88% | 99% | Complies |
| **2** | MAN/AMX T/04.07.2 023/018 | Amoxicillin DT | Remedica LTD | 100515 | 054 | 183 | None deviates | 99% | 98-100% | 99.2%% | Complies |
| **3** | GAR/AMX T/30.06.2 023/004 | Amoxicillin 250mg USP tablets | Reyoung | 2231310 97 | 052 | 182 | None deviates | 97% | 96-98% | 97.00% | Complies |

### 4.4.4.7 Cetirizine Tablets

**Table 17:** Analysis Results for Cetirizine tablets

| S/N | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/2 023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| | | | | | | | | Average | Range | | |
| 1 | BUS/CTZT/ 01.07.2023 /023 | Rhizin | Ravian Lifescience Pvt Ltd | EKERH 22001 | 085 | 149 | None Deviates | 92% | 91.8-92.4% | 93.40% | Complies |
| 2 | LAM/CTZT/ 04.07.2023 /006 | Cetriz-10 | Laboratory & Allied | 80657 | 087 | 147 | One deviates (10.1%) | 95% | 95-96% | 93.20% | Complies |

| S/N | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| | | | | | | | | Average | Range | | |
| 3 | BUS/CTZT/01.07.2023/019 | Cetriz-10 | Laboratory & Allied | 82815 | 088 | 151 | None Deviates | 93% | 93-93.4% | 93.50% | Complies |
| 4 | BUN/CTZT/02.07.2023/034 | Cachcet | Cachet Pharmaceuticals Pvt Ltd | CCT22030E | 086 | 148 | None Deviates | 87% | 86-87% | 96.70% | Complies |
| 5 | SIA/CTZT/02.07.2023/025 | Rizexin | Comet Healthcare Limited | 30624 | 089 | 146 | None Deviates | 96% | 94-98% | 95.70% | Complies |
| 6 | NAI/CTZT/28.06.2023/005 | Zyncet | Unichem Laboratories Ltd | BZN-22027 | 090 | 145 | None Deviates | 96% | 95.5-96.1% | 94.20% | Complies |
| 7 | NAI/CTZT/28.06.2023/006 | Galcet | Fredun Pharmaceuticals Ltd | AD0320 | 091 | 144 | None Deviates | 86% | 85-86% | 95.80% | Complies |

### 4.4.4.8 Enalapril Tablets

**Table 18:** Analysis Results for Enalapril tablets

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| 1 | KIA/ELPT/03.07.2023/017 | Encardil 5 | Medley Pharmaceuticals Ltd | D20552 | 062 | 169 | None Deviates | 103% | 102-103% | 98.30% | Complies |
| 2 | NAI/ELPT/28.06.2023/019 | Encardil 10 | Medley Pharmaceuticals Ltd | D20468 | 064 | 171 | None Deviates | 101% | 99-106% | 98.40% | Complies |
| 3 | LAM/ELPT/04.07.2023/003 | Cardace 5 | Cosmos Limited | 212142 | 066 | 172 | None Deviates | 101% | 99-102% | 97.10% | Complies |
| 4 | SIA/ELPT/02.07.2023/029 | Acepril 5 | Laboratory & Allied Ltd | 81515 | 067 | 173 | None Deviates | 92% | 87-96% | 101.40 % | Complies |
| 5 | MSA/ELPT/30.06.2023/032 | Enapril 10 | Intas Pharmaceuticals Ltd | D2200684 | 068 | 174 | None Deviates | 101% | 99-108% | 101.10 % | Complies |
| 6 | GAR/ELPT/30.06.2023/007 | Vasopril 10 | Square Pharmaceuticals Ltd | 2H03734 | 069 | 175 | None Deviates | 88% | 86-90% | 92.90% | Complies |

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| 7 | BUS/ELPT/ 01.07.2023 /024 | Encardil 5 | Medley Pharmaceuticals Ltd | D20466 | 070 | 176 | None Deviates | 100% | 99-101% | 101.40 % | Complies |
| 8 | MSA/ELPT/ 30.06.2023 /023 | Enril 5 | Prism Lifesciences Limited | KN532 | 065 | 256 | None Deviates | 81% | 80-83% | 81.5% | **Does NOT comply** |
| 9 | NYE/ELPT/ 29.06.2023 /007 | Enaril 5 | Beximco Pharmaceuticals Ltd | 11234891 | 063 | 170 | None Deviates | 91% | 90-92% | 100.20 % | Complies |

### 4.4.4.9 Paracetamol tablets

**Table 19:** Analysis Results for Paracetamol tablets

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| 1 | KIA/ELPT/ 03.07.2023 /017 | Encardil 5 | Medley Pharmaceuticals Ltd | D20552 | 062 | 169 | None Deviates | 103% | 102-103% | 98.30% | Complies |

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| 2 | NAI/ELPT/ 28.06.2023 /019 | Encardil 10 | Medley Pharmaceuticals Ltd | D20468 | 064 | 171 | None Deviates | 101% | 99-106% | 98.40% | Complies |
| 3 | LAM/ELPT /04.07.2023/003 | Cardace 5 | Cosmos Limited | 212142 | 066 | 172 | None Deviates | 101% | 99-102% | 97.10% | Complies |
| 4 | SIA/ELPT/ 02.07.2023 /029 | Acepril 5 | Laboratory & Allied Ltd | 81515 | 067 | 173 | None Deviates | 92% | 87-96% | 101.40% | Complies |
| 5 | MSA/ELPT /30.06.2023/032 | Enapril 10 | Intas Pharmaceuticals Ltd | D2200684 | 068 | 174 | None Deviates | 101% | 99-108% | 101.10% | Complies |
| 6 | GAR/ELPT /30.06.2023/007 | Vasopril 10 | Square Pharmaceuticals Ltd | 2H03734 | 069 | 175 | None Deviates | 88% | 86-90% | 92.90% | Complies |
| 7 | BUS/ELPT /01.07.2023/024 | Encardil 5 | Medley Pharmaceuticals Ltd | D20466 | 070 | 176 | None Deviates | 100% | 99-101% | 101.40% | Complies |
| 8 | NYE/ELPT /29.06.2023/007 | Enaril 5 | Beximco Pharmaceuticals Ltd | 11234891 | 063 | 170 | None Deviates | 91% | 90-92% | 100.20% | Complies |

### 4.4.4.10 Ciprofloxacin tablets

**Table 20:** Analysis Results for Lorsartan tablets

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/2023-24/ | Test results | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of weight | Dissolution | | Assay | |
| 1 | KIA/CPFT/03.07.2023/028 | Ciproglax | Galaxy Pharmaceuticals Ltd | CB0094 | 059 | 180 | None deviates | 93% | 91 - 95% | 97.00% | Complies |
| 2 | MIG/CPFT/04.07.2023/040 | Ciprodeal | Biodeal Laboratories Ltd | 1022012 | 057 | 165 | None deviates | 93% | 91 —95% | 94.70% | Complies |
| 3 | BUN/CPFT/02.07.2023/038 | Comcip | Comet healthcare ltd | 30412 | 061 | 164 | None deviates | 94% | 92 - 96% | 94.50% | Complies |
| 4 | NAI/CPFT/28.06.2023/008 | Shalcip | Shalina Laboratories PVT. Ltd | 1371686 | 060 | 167 | None deviates | 96% | 95 - 98% | 96.30% | Complies |
| 5 | KAJ/CPFT/03.07,2023/048 | Guciprox | Gullin Pharmaceuticals CO., Ltd. | HB230403 | 058 | 166 | None deviates | 95% | 94 -- 96% | 102.40% | Complies |

### 4.4.4.11 Levonorgestrel tablets

**Table 21:** Analysis Results for Levonorgestrel tablets

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/2023-24/ | Test results | | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Uniformity of content | Uniformity of weight | Dissolution | | Assay | |
| | | | | | | | | | Average | Range | | |
| 1 | KIA/LVGT/03.07.2023/021 | Emcon | Renata Limited | H0822008 | 100 | 199 | AV - 11.5 | None deviates | 96% | 94 -98% | 101.00 % | Complies |
| 2 | NAI/LVGT/28.062023/020 | Preynilo c | Combitic Global Caplet Pvt, Ltd | PNC-06 | 101 | 200 | AV = 4.1 | None deviates | 84 % | 81 -88% | 99.3 % | Complies |
| 3 | NYE/LVGT/30.06.2023/016 | Safe-72tm | Ovation Remedies | OHT-006 | 102 | 201 | AV =1.1 | None deviates | 96% | 92-99% | 99.8 % | Complies |
| 4 | KWA/LVGT/29.06.2023/011 | Ecee 2 | Zydus Healthcare Limited | 6200896 | 103 | 202 | AV =1.7 | None deviates | 90% | 88 -93% | 98.5 % | Complies |

### 4.4.4.12 Male latex condoms

**Table 22:** Analysis Results for Male latex condoms

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Quantity of lubricant | | Dimensions | | Burst volume and pressure | | Freedom from holes | |
| | | | | | | | Mean | Range | Mean | Range | Mean | Average | | |
| 1 | MSA/MLC/30.06.2023/024 | Kiss Classic | Thai Nippon Rubber Industry PLC | L33221101 | 105 | 192 | 508 mg/ condom | 493 - 528 mg/ condom | 196 mm | 193 — 200 mm | 32.5 L | 18.5 - 41.0 L | 1 Deviates | Complies |
| 2 | BUS/MLC/01.07.2023/025 | Trusttm Classic | HLL Lifecare Limited | Y45RG044 | 106 | 193 | 522 mg/ condom | 500-529 mg/condom | 196 mm | 192 - 199 mm | 31.5 L | 1.5 - 40.5 L | None deviates | Complies |
| 3 | KIA/MLC/04.07.2023/037 | Sure® Lubricated Condoms Dotted | HLL Lifecare Limited | Y48130 | 107 | 194 | 503 mg/ condom | 488-514 mg/ condom | 196 mm | 195 - 198 mm | N/A | N/A | N/A | Complies |
| 4 | NAI/MLC/28.06.2023/029 | Kiss Classic Lubricated | Thai Nippon Rubber Industry PLC | L32221102 | 108 | 195 | 507 mg/ condom | 496 - 520 mg/ condom | 195 mm | 195 - 197 mm | 29.0 L | 0.0-37.0 L | None deviates | Complies |

| | Unique sample code | Brand Name | Name of manufacturer | Batch Number | NDQA 202308- | CAN/ 2023-24/ | Test results | | | | | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Quantity of lubricant | | Dimensions | | Burst volume and pressure | | Freedom from holes | |
| | | | | | | | Mean | Range | Mean | Range | Mean | Average | | |
| | | Condoms | | | | | | | | | | | | |
| 5 | LAM/MLC/04.07.2023/009 | Sure® Lubricated Condoms Dotted | HLL Lifecare Limited. | Y48132 | 109 | 196 | 519 mg/ condom | 500 - 528 mg/ condom | 197 mm | 194 - 200 mm | 273 L | 8.0 - 38.5 L | None deviates | Complies |
| 6 | KIS/MLC/01.07.2023/017 | Trusttm Classic Condoms | Penta Latex LLPw | 5JEIV003 | 110 | 197 | 538 mg/ condom | 446 - 613 mg/ condom | 199 mm | 192 - 197 mm | 26.6 L | 1.5 - 39.0 L | None deviates | Complies |

## 5.0 DISCUSSION

A total of two hundred and seventy nine (279) primary samples were collected from a total of one-hundred and fifty eight (158) facilities comprising of one-hundred and forty two (142) private facilities, Fourteen (14) public facilities and two (2) Faith Based Organizations (FBOs) spread across fifteen (15) counties.

One hundred and seventy one (171) samples were subjected to minilab testing, representing 61.29% of the total samples collected. The samples that were analyzed included Amoxicillin, Paracetamol, Ciprofloxacin, Losartan, Omeprazole and Cetirizine. Five (5) samples of Omeprazole capsules had doubtful results at the initial field screening using the TLC technique, they were submitted to the PPB quality laboratory for verification testing. The verification test results showed the samples complied with all the test parameters analyzed.

A total of seventy-two (72) samples were submitted to the National quality control laboratory for compendial testing. Out of the seventy-one (71) samples analyzed , All except one sample complied with specifications for all the test parameters analyzed. The sample that failed to comply is Enril-5 (Enalapril 5 mg) , batch No. KN532 which is manufactured by Prism Lifesciences Limited, India. The product failed assay test ( 81.5%, while the specification limits are 90.0 – 110). The PPB initiated immediate recall of the product from the Kenyan market.

## 6.0 RECOMMENDATION

i. The PPB post-market surveillance team should conduct more training and awareness to the healthcare workers on reporting and patient record management.
ii. Consider an extended timeline for future PMS activities in certain regions due to the uniqueness of the regio
iii. The sample and data collection teams recommended includiosnof the exact location of facilities including road and building
iv. The sample and data collection teams recommended that regular. Updating of the master facility list should be done to ensure accuracy of the status of healthcare facilities, whether operational or Not.

v. Implementation of routine post-marketing surveillance activities should be conducted more regularly.

## 7.0 CONCLUSION

The post-market surveillance quality survey focused on Antimicrobials (Amoxicillin and ciprofloxacin), Anti-cancer agents (Doxorubicin), Antihypertensives (Enalapril and Losartan), Analgesics (Paracetamol), contraceptives. (Levonorgestrel), Anti-histamines (Cetirizine) and anti-ulcer medicines (Omeprazole). The medical devices include the male latex condoms. The samples were analyzed based three-tier risk based testing approach. All the samples that were analyzed using MiniLabs complied with all the test parameters analyzed while all except one sample complied with all specifications for all the test parameters analyzed for samples subjected to compendial testing.

The continuous monitoring of the quality of HPTs in the Kenyan market is critical in ensuring and assuring their safety and efficacy and hence achieving desirable patient outcomes as well as enhancing confidence in the healthcare delivery system.

## 8.0 REFERENCES

1. A Risk-Based Resource Allocation Framework for Pharmaceutical Quality Assurance for Medicines Regulatory Authorities in Low- and Middle-

Income Countries: https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based_resource_allocation_framework_june2018.pdf

2. Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B., & Van Damme, W. "Access to medicines from a health system perspective. ." Health policy and planning. 28.7 (2013): 692-704.
3. Good practices for pharmaceutical quality control laboratories. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fourth report. Geneva: World Health Organization; 2010: Annex 1 (WHO Technical Report Series, No. 957 (http://www.who.int/prequal/info_general/documents/TRS957/GPCL _TRS957_Annex1.pdf, accessed 30 October 2018).
4. Post-market surveillance report on quality survey of Medicines available in selected IGAD cross- border sites; June 2019.
5. Promoting the Quality of Medicines (PQM) Program: Guidance for implementing Risk-Based Post- Marketing Quality Surveillance in Low- and -Middle -Income -Countries: https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based-post-marketing-surveillance-feb-2018.pdf
6. Sachs, J. D. "From millennium development goals to sustainable development goals." The lancet 379.9832 (2012): 2206-2211.
7. WHO Guideline on the Conduct of Surveys of the Quality of Medicines (WHO-TRS number 996, 2016, Annex 7). World Health Organization: http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_web.pdf
8. WHO Guidelines for Sampling of Pharmaceutical Products and Related Materials (WHO 631 Technical Report Series, No. 929, 2005, Annex 4). World Health Organization: http://apps.who.int/medicinedocs/en/d/Js21440en/.
9. http://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified (Accessed on 9th August, 2018).

10. Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. WHO, Geneva. WHO/EMP/QSM/2011.1. www.who.int/medicines/publications/WHO_QAMSA_report.pd.
11. Wirtz VJ, Hogerzeil HV, Gray AL, Bigdeli M, de Joncheere CP, Ewen MA, et al. Essential medicines for universal health coverage. Lancet. 2017; 389:403-76. http://www.ghtcoalition.org/pdf/Essential-medicines-for-universal-health-coverage.pdf.
12. http://www.pharmacyboardkenya.org/postmarket_surveillance (Accessed on 9th August, 2018).
13. Leonard Manirakiza, Victoria Nambasa, Stella Nanyonga, Allan Serwanga, Matovu Alphonsus, Nankola Denis, Helen Ndagije. Drug Use Evaluation (DUE) of Ceftriaxone in Mubende Regional Referral Hospital, Uganda: A Cross-Sectional Survey. J Pharm Pharmacol Res 3 (2019): 105-115.
14. Ampaire L, Muhindo A, Orikiriza P, Mwanga-Amumpaire J, Bebell
15. WHO. Kenya NCD Country Profile. 2018
16. Global cancer observatory report (Globocan 2020)
17. https://gco.iarc.fr/today/data/factsheets/populations/404-kenya-fact-sheets.pdf
18. https://www.health.go.ke/wp-content/uploads/2022/07/National-Cancer-Taskforce-Report-July-2022.pdf (accessed on 16th February 2023
19. Kenya essential medicines list 2019
20. https://www.cancer.gov/about-cancer/treatment/drugs/doxorubicinhydrochloride
21. Mohamed SF, Mutua MK, Wamai R, Wekesah F, Haregu T, Juma P, Nyanjau L, Kyobutungi C, Ogola E. Prevalence, awareness, treatment and control of hypertension and their determinants: results from a national survey in Kenya. BMC Public Health. 2018 Nov 7;18(Suppl 3):1219. doi: 10.1186/s12889-018-6052-y. PMID: 30400858; PMCID: PMC6219055

22. Phillips-Howard PA, Laserson KF, Amek N, Beynon CM, Angell SY, Khagayi S, et al. Deaths ascribed to non-communicable diseases among rural Kenyan adults are proportionately increasing: evidence from a health and demographic surveillance system, 2003–2010. PLoS One. 2014;9(11):e114010. doi: 10.1371/journal.pone.0114010. [PMC free article][PubMed] [CrossRef] [Google Scholar
23. Institute for Health Metrics and Evaluation and the International Centre for Humanitarian Affairs. The Global Burden of Disease: Generating Evidence, Guiding Policy in Kenya. Nairobi, Kenya; 2016
24. http://erepository.uonbi.ac.ke/bitstream/handle/11295/96173/Gathiru_The%20Prevalence%20Of%20Allergic%20Rhinitis%20In%20College%20Students%20At%20Kenya%20Medical%20Training%20Clloege%20(Kmtc)%20-%20Nairobi.pdf?sequence=
25. https://www.ncbi.nlm.nih.gov/books/NBK549776
26. [1] Ampaire, L., Muhindo, A., Orikiriza, P., Mwanga-Amumpaire, J., Bebell, L., & Boum, Y. (2016). A review of antimicrobial resistance in East Africa. African journal of laboratory medicine, 5(1), 432. https://doi.org/10.4102/ajlm.v5i1.432

## 9.0 ANNEXES

**Annex 1**: 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:<br>**(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 #: (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 forms: 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:<br>(Use name in MFL list if applicable) | | | |
| Sector of Facility<br>(Public, Private, Informal) | | | |
| Type of Facility<br>(Hospital, Health Center) | | | |
| Contact Person:<br>(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?<br>YES NO | | | |
| Storage Temperature: | | | |

| | |
|---|---|
| (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:***

*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:** Visual and physical inspection and MiniLab results form


| **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] _____ | ○ Less than 80%<br>○ Between 80% and 100%<br>○ More than 100%<br>Were there any contaminants/impurities present?<br>☐ Yes ☐ No<br>Observations: _____ |
| **FINAL RESULTS** | |
| ○ The sample conformed with basic tests<br>○ The sample did not conform with basic tests Reason: _____<br>○ The sample is considered doubtful Reason: _____ | |
| How many units are remained after basic tests? _____ | |
| **REPORT REVIEWED BY[6]:** | |
| Name: _____ Signature: _____<br>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

## Addendum 4: Sampling instructions

*Sampling instructions*

i. An item collected from a medicine (identified by the name, content of APIs, dosage form, strength, batch number and manufacturer) at the same collection site is called a sample. **All dosage units of one sample must be of the same batch**, there should not be a mix-up with batches. In the case that in a collection site the

required number of packages of the same batch is not available, sample of that particular medicine is not collected from that site

ii. Collect dosage forms and strengths specified in the post-marketing surveillance protocol only

iii. If there is more than one pack size per medicine or medical device available for the particular product in the country, it is sufficient to collect one of them. In principle biggest pack sizes should be collected.

iv. As far as possible diversify the samples of products from various manufacturers rather than several batches produced by one manufacturer. If more than three products are available for sampling:

1. the most unlikely quality assured products should be collected,

v. Samples collected shall have at least six months remaining shelf life. Products with shorter period remaining to expiry date will not be collected.

vi. Only unopened original packages shall be collected.

vii. Medicine samples shall not be taken out of the original primary packaging and outer containers (though removal of blisters from large secondary packs is appropriate). Containers such as bottles shall not be opened.

viii. Sampling shall be recorded using the sample collection form. Whenever the required information is not available, it should be indicated by "NA" in the appropriate space on the sample collection form. Any abnormalities should be recorded.

ix. Each sample will be identified by a unique sample code *(for coding system see the sample collection form, Addendum II)* specified in the sample collection form as well as on all the original packages belonging to the respective sample (legible and not covering basic sample information). Packages belonging to one sample and sample

collection form will be kept together (e.g., blisters inserted in a dedicated envelope marked with the appropriate unique sample code).

x. During sample collection the storage conditions at the site should be evaluated and described in the sample collection form.

xi. Manufacturer's batch certificates of analysis will be collected with samples, if available, and kept with the sample collection form. Any other available results of analysis of the collected batch (pre- or post-shipment, testing by procurers or other NRAs) should also be collected with samples and kept with the sample collection form.

xii. The samples should be collected and kept under manufacturers recommended storage conditions. Collected samples should be submitted to testing laboratory within the shortest time period.

**Annex 4:** Product information review (PIR) form

| **Pharmacy and Poisons Board** | **Product information review (PIR) form** | **FOM047/HPT/PDS/VMS/SOP/011** |
|---|---|---|
| | | Rev No. 0 |

**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<br>Name & Physical address | |
| Storage conditions | |

| **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<br>(Specify only if different from the external packaging under point 1) | YES NO<br>…… |

| | |
|---|---|
| | |

**3. REGISTRATION AND RETENTION STATUS**

| | | |
|---|---|---|
| REGISTRATION | YES | NO |
| RETENTION | YES | NO |

**4. PACKAGE LEAFLET INFORMATION**

| **4- Package leaflet** | |
|---|---|
| Presence of the leaflet | YES NO |
| Language(s) of the leaflet | ..... |
| Composition | YES NO |
| Manufacturer name & physical address<br>(Specify only if different from the external packaging under point 1) | YES NO<br>.....<br>..... |
| Storage conditions<br>(Specify only if different from the external packaging under point 1) | YES NO<br>.....<br>..... |

**4- Observation on any discrepancy between the above points 1, 2 or 3 or non-compliance, if any (such as uniformity of words and font size used in labeling, color of packaging materials etc)**

**Annex 5:** Report format for PMS field activity

**PMS Field activity report**

Date of the report

**Activity dates:**

**Name of sample collectors:**

1. _____
2. _____

**Subject: Report on field activity for post-marketing quality survey of health products and technologies in Kenya**

**Background:**

The following is summary of the activities performed during the trip:

**1. Names of counties visited**

**2.Duration of the Sample collection activity: From _____to_____**

**3. Samples collected from the sampling sites**

| S/N | Medicines name (INN) | # Samples targeted to be collected from the site | # Actual Samples collected from the sites | Remark |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**4. Sampling facilities visited during the sample collection**

**5. Facilities that were substituted and reasons for substitution**

**6. Successes**

**6.Challenges**

The following were the main challenges the team faced during the sample collection:

**7. Recommendations**

Annex 1: List of samples submitted to_____

Prepared by: _____

Signature and date

**Annex 6:** List of sampling facilities

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 1 | Nyeri | Nyeri Late Night Chemist | Nyeri town | Private | Retail pharmacy |
| 2 | Nyeri | Mizizi pharmacy | Nyeri town | Private | Retail pharmacy |
| 3 | Nyeri | Petrinah pharmacy | Nyeri town | Private | Retail pharmacy |
| 4 | Nyeri | Karen Hospital | Nyeri town | Private | Hospital pharmacy |
| 5 | Nyeri | Bliss Medical Centre | Nyeri town | Private | Hospital pharmacy |
| 6 | Nyeri | Central Dialysis Centre | Nyeri town | Private | Hospital pharmacy |
| 7 | Nyeri | Outspan Hospital | Nyeri town | Private | Hospital pharmacy |
| 8 | Nyeri | Eland Pharmacy | Nyeri town | Private | Retail pharmacy |
| 9 | Nyeri | Hallel Pharmacy | Mathira | Private | Retail pharmacy |
| 10 | Nyeri | Jamii hospital | Mathira | Private | Hospital pharmacy |
| 11 | Nyeri | Habi Dispensing Chemist | Kieni | Private | Retail pharmacy |
| 12 | Nyeri | Mukurweini hospital | Mathira | Public | Hospital pharmacy |
| 13 | Nyeri | Tumu Tumu Mission Hospital | Mathira | FBO | Hospital pharmacy |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 14 | Nyeri | Philmed Pharmacy | Mathira | Private | Wholesaler |
| 15 | Kiambu | ALL PHARMA PHARMACY | Thika town | Private | Retail pharmacy |
| 16 | Kiambu | Joywin chemist | Thika town | Private | Retail pharmacy |
| 17 | Kiambu | ALLMED HEALTHCARE LTD | | Private | Retail pharmacy |
| 18 | Kiambu | Juja Modern Hospital | juja town | Private | Hospital pharmacy |
| 19 | Kiambu | Meds Hope Pharmacy | Ruiru | Private | Retail pharmacy |
| 20 | Kiambu | Kavakava Pharmacy | Githurai 44 | Private | Retail pharmacy |
| 21 | Kiambu | Kiambu Level 5 Hospital | Kiambu town | Public | Hospital pharmacy |
| 22 | Kiambu | Kiambu Level 5 Hospital | Kiambu town | Public | Hospital pharmacy |
| 23 | Kiambu | karura Chemist-Wangige | Wangige Market | Private | Retail pharmacy |
| 24 | Kiambu | Wagachem Pharmaceuticals Ltd | Wangige Market | Private | Retail pharmacy |
| 25 | Garissa | Markaz Pharmacy | Garissa Township | Private | Wholesaler |
| 26 | Garissa | Al-farouq Dispensary | Garissa Township | Public | Hospital pharmacy |
| 27 | Garissa | Garissa County Referral Hospital | Garissa Township | Public | Hospital pharmacy |
| 28 | Garissa | Deltat Supermeds CHEMIST | Garissa Township | Private | Retail pharmacy |
| 29 | Garissa | Antaliya Hospital | Garissa Township | Private | Hospital pharmacy |
| 30 | Garissa | Madina Health Centre | Bulla Madina | Public | Hospital pharmacy |
| 31 | Garissa | Ummah Pharmacy-Corner Plaza | Garissa Township | Private | Retail pharmacy |
| 32 | Garissa | Makkah Pharmaceutical Ltd | Garissa Township | Private | Wholesaler |
| 33 | Garissa | Safnaan Pharmaceutical limited | Garissa Township | Private | Retail pharmacy |
| 34 | Garissa | Medina Pharmacy Ltd | Garissa Township | Private | Wholesaler |
| 35 | Mandera | Bluelight Pharmacy | Mandera town | Private | Hospital pharmacy |
| 36 | Mandera | Mandera County Referral Hospital | Mandera town | Public | Hospital pharmacy |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 37 | Mandera | Mandera drugmart ltd | Mandera town | Private | Retail pharmacy |
| 38 | Mandera | Shamaal hospital | Mandera town | Private | Hospital pharmacy |
| 39 | Mandera | Mandera wellness centre | Mandera town | Private | Hospital pharmacy |
| 40 | Mandera | The virgin pharmaceuticals LTD | Mandera town | Private | Retail pharmacy |
| 41 | Mandera | The mandera hospital | Mandera town | Private | Hospital pharmacy |
| 42 | Mandera | Al-siha Nursing Home | Mandera town | Private | Hospital pharmacy |
| 43 | Vihiga | Tigoi Chemists | Tigoi | Private | Retail pharmacy |
| 44 | Vihiga | Mungoma Hospital | Majengo | Private | Hospital pharmacy |
| 45 | Vihiga | Texvillah | Majengo | Private | Retail pharmacy |
| 46 | Vihiga | Vihiga County Referral Hospital | Mbale | Public | Hospital pharmacy |
| 47 | Vihiga | Across Western Pharmaceuticals Ltd | Mbale | Private | Wholesaler |
| 48 | Vihiga | Bliss Medical Centre | Mbale | Private | Hospital pharmacy |
| 49 | Vihiga | Kima Mission Hospital | Luanda | FBO | Hospital pharmacy |
| 50 | Vihiga | Equator Medical Services | Luanda | Private | Hospital pharmacy |
| 51 | Vihiga | Vihiga Drug Mart | Luanda | Private | Wholesaler |
| 52 | Vihiga | Kunj Enterprise | Luanda | Private | Retail pharmacy |
| 53 | Busia | Busia County Referral Hospital | Matayos | Public | Hospital pharmacy |
| 54 | Busia | Drogen Pharmacy | Busia | Private | Retail pharmacy |
| 55 | Busia | Jaspa Pharmacy | Busia | Private | Retail pharmacy |
| 56 | Busia | Medisca Pharmacy Ltd | Busia | Private | Retail pharmacy |
| 57 | Busia | Busia Vision Pharmacy | Busia | Private | Retail pharmacy |
| 58 | Busia | Walmart Pharmacy | Matayos | Private | Retail pharmacy |
| 59 | Busia | Busia Medical Specialist Diagnostic Centre | Matayos | Private | Retail pharmacy |
| 60 | Busia | Amo Malaba Pharmacy | Malaba | Private | Retail pharmacy |
| 61 | Busia | Haman Chemist Ltd | Malaba | Private | Retail pharmacy |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 62 | Busia | Zoticed Enterprises | Malaba | Private | Wholesaler |
| 63 | Busia | Appex Hospital Malaba | Malaba | Private | Hospital pharmacy |
| 64 | Busia | Bungoma Chemist | Malaba | Private | Retail pharmacy |
| 65 | Bungoma | Dovas Pharmacy | Bungoma | Private | Retail pharmacy |
| 66 | Bungoma | Khalaba Medical Services | Bungoma | Private | Hospital pharmacy |
| 67 | Bungoma | Bungoma County Referral Hospital | Bungoma | Public | Hospital pharmacy |
| 68 | Bungoma | Bungoma West Chemist | Bungoma | Private | Retail pharmacy |
| 69 | Bungoma | Chwele Yanja Chemist | Chwele | Private | Retail pharmacy |
| 70 | Bungoma | Eyat Royal Pharmacy | Webuye | Private | Retail pharmacy |
| 71 | Bungoma | Webuye County Hospital | Webuye | Public | Hospital pharmacy |
| 72 | Vihiga | Mungoma Chemist | Mbale | Private | Retail pharmacy |
| 73 | Kajiado | Gondian Pharmaceuticals | Kitengela town | Private | Retail pharmacy |
| 74 | Kajiado | Lenana Pharmacy | Kitengela town | Private | Wholesaler |
| 75 | Kajiado | Drugheal Chemist | Isinya town | Private | Retail pharmacy |
| 76 | Kajiado | Haltons Pharmacy | Kiserian town | Private | Retail pharmacy |
| 77 | Kajiado | Topline Pharmaceuticals | Kiserian town | Private | Wholesaler |
| 78 | Kajiado | Chemrex Pharamcy | Ngong Town | Private | Retail pharmacy |
| 79 | Kwale | Msambweni County Referral Hospital | Kwale | Public | Hospital pharmacy |
| 80 | Kwale | Ochieng Chemist Ltd Ibiza | Ibiza | Private | Retail pharmacy |
| 81 | Kwale | Diani Chemist | Ukunda | Private | Retail pharmacy |
| 82 | Kwale | Zelian Pharmacy | Ukunda-Diani Road | Private | Retail pharmacy |
| 83 | Kwale | Diani Beach Hospital | Diani | Private | Hospital pharmacy |
| 84 | Kwale | Diani Beach Hospital-Clinic | Ukunda | Private | Hospital pharmacy |
| 85 | Kwale | Nature Ayurvedic Remedies | Likoni-Lunga Lunga Road | Private | Retail pharmacy |
| 86 | Kwale | Ochieng Chemist Ltd Ukunda | Ukunda | Private | Retail pharmacy |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 87 | Kwale | South Road Pharmaceuticals Ltd | Likoni-Lunga Lunga Road | Private | Retail pharmacy |
| 88 | Mombasa | Wayside Pharmacy | Bamburi | Private | Retail pharmacy |
| 89 | Mombasa | Ace Northern Hospital | Bamburi | Private | Hospital pharmacy |
| 90 | Mombasa | Makadara Chemist | Mombasa-Kilifi road | Private | Retail pharmacy |
| 91 | Mombasa | Premier Hospital | Links Road-Nyali | Private | Hospital pharmacy |
| 92 | Mombasa | Coast General Hospital | Kisauni Road-Tononoka Mombasa Town | Public | Hospital pharmacy |
| 93 | Mombasa | Njimia Pharmaceuticals Ltd | Digo Road,Mombasa Town | Private | Retail pharmacy |
| 94 | Mombasa | Shifa Chem Ltd | Mvita - Mombasa Town | Private | Wholesaler |
| 95 | Mombasa | Fusam Retail Chemist | Jomo Kenyatta Road-Mvita | Private | Retail pharmacy |
| 96 | Mombasa | Rangechem Makadara | Moi avenue-Mombasa Town | Private | Retail pharmacy |
| 97 | Mombasa | Faiz Pharmacy Ltd | Nkhuruma road,Mombasa Town | Private | Retail pharmacy |
| 98 | Mombasa | Bombolulu Life care Pharmacy | Bombolulu | Private | Retail pharmacy |
| 99 | Mombasa | Transwide Pharmaceuticals Ltd-Mombasa | Jomo-Kenyatta Avenue Mombasa Town | Private | Wholesaler |
| 100 | Mombasa | Badar Pharmacy Ltd | Makadara street-Mombasa Town | Private | Retail pharmacy |
| 101 | Mombasa | Eldo-Hosp Pharmaceuticals | Nyerere Avenue-Mombasa Town | Private | Wholesaler |
| 102 | Lamu | Lamu County Referral Hospital | Lamu Town | Public | Hospital pharmacy |
| 103 | Lamu | Ibnusina Pharmacy | Lamu Town | Private | Retail pharmacy |
| 104 | Lamu | Nilson Chemist | Lamu Town | Private | Retail pharmacy |
| 105 | Kisumu | Ahero County Hospital | Ahero town | Public | Hospital pharmacy |
| 106 | Kisumu | Kentons | Kisumu town | Private | Wholesaler |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 107 | Kisumu | A to Z Pharmacy Ltd | Kisumu town | Private | Wholesaler |
| 108 | Kisumu | Unam Medical Centre | Kisumu town | Private | Hospital pharmacy |
| 109 | Kisumu | AAR Healthcare Ltd- Kisumu | Kisumu town | Private | Hospital pharmacy |
| 110 | Kisumu | Tayiba Medical Centre | Kisumu town | Private | Hospital pharmacy |
| 111 | Kisumu | St. Luke'S Hospital | Kisumu town | Private | Hospital pharmacy |
| 112 | Kisumu | Jaramogi Oginga Odinga Teaching and Referral Hospital | Kisumu town | Public | Hospital pharmacy |
| 113 | Kisumu | Medio Care Pharmaceuticals | Kisumu town | Private | Wholesaler |
| 114 | Kisumu | Victoria Healthcare Ltd | Kisumu town | Private | Wholesaler |
| 115 | Kisumu | Miriu Chemist Ltd- Kisumu | Kisumu town | Private | Retail pharmacy |
| 116 | Kisumu | Fairmont Hospital | Kisumu town | Private | Hospital pharmacy |
| 117 | Kisumu | Tridev Pharmaceuticals Ltd | Kisumu town | Private | Wholesaler |
| 118 | Kisumu | Max cure Hospitals Limited | Kisumu town | Private | Hospital pharmacy |
| 119 | Kisumu | Maclyn Healthcare Services | Kisumu town | Private | Hospital pharmacy |
| 110 | Kisumu | Chiral Chemist | Kisumu town | Private | Retail pharmacy |
| 119 | Kisumu | Maya's Pharmaceuticals | Kisumu town | Private | Retail pharmacy |
| 120 | Siaya | Medio Care Pharmaceuticals Ltd - Bondo | Bondo town | Private | Retail pharmacy |
| 121 | Siaya | Medio Care Pharmaceuticals Ltd - Bondo | Bondo town | Private | Retail pharmacy |
| 122 | Siaya | GEDMED MEDICAL CENTRE LTD (SIAYA DRUG STORE) | Siaya town | Private | Retail pharmacy |
| 123 | Siaya | Oasis Multispecialist Hospital | Siaya town | Private | Hospital pharmacy |
| 124 | Siaya | Nyakan Pharmacy Stores | Siaya town | Private | Retail pharmacy |
| 125 | Siaya | Facol Chemist | Siaya town | Private | Retail pharmacy |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 126 | Siaya | Geka Pharm Pharmacy | Lwanda town | Private | Retail pharmacy |
| 127 | Siaya | Olympus Medical Centre | Yala town | Private | Hospital pharmacy |
| 128 | Siaya | Ambira Sub-County Hospital | Ugunja town | Public | Hospital pharmacy |
| 129 | Siaya | Bondo Sub-County Hospital | Bondo town | Public | Hospital pharmacy |
| 130 | Migori | Silverlane Chemist | Rongo town | Private | Retail pharmacy |
| 131 | Migori | Mamo Pharmaceuticals | Rongo town | Private | Retail pharmacy |
| 132 | Migori | Royal Medical Clinic & Maternity Home | Rongo town | Private | Hospital pharmacy |
| 133 | Migori | Monicare Pharmacy Enterprises | Awendo town | Private | Retail pharmacy |
| 134 | Migori | Dancuns Chemist | Awendo town | Private | Retail pharmacy |
| 135 | Migori | Awendo Sub-County Hospital | Awendo town | Public | Hospital pharmacy |
| 136 | Migori | Madala Pharmacy | Awendo town | Private | Retail pharmacy |
| 137 | Migori | Henris Chemistry | Uriri town | Private | Retail pharmacy |
| 138 | Migori | Sori Lakeside Pharmacy | Sori town | Private | Retail pharmacy |
| 139 | Migori | Handshake Pharmaceuticals | Migori town | Private | Retail pharmacy |
| 140 | Kisii | Transchem Pharmaceutical Limited | Nairobi | Private | Retail pharmacy |
| 141 | Nairobi | Estel Pharmacy | Nairobi | Private | Retail pharmacy |
| 142 | Nairobi | Diamed Pharmaceuticals | Nairobi | Private | Retail pharmacy |
| 143 | Nairobi | Cefa Chem Pharmacy | Nairobi | Private | Retail pharmacy |
| 144 | Nairobi | Hemlocc Pharmacy | Nairobi | Private | Retail pharmacy |
| 145 | Nairobi | Briana Pharmacy | Nairobi | Private | Retail pharmacy |
| 146 | Nairobi | Geel Pharmacy | Nairobi | Private | Retail pharmacy |
| 147 | Nairobi | Philmed Pharmacy | Nairobi | Private | Retail pharmacy |
| 148 | Nairobi | States Pharmacy | Nairobi | Private | Retail pharmacy |
| 149 | Nairobi | Marine Pharmacy | Nairobi | Private | Retail pharmacy |
| 150 | Nairobi | Tpeachwood Pharmacy | Nairobi | Private | Retail pharmacy |

| S/N | County | Name of Facility | Location of Facility | Sector of Facility | Type of Facility |
|---|---|---|---|---|---|
| 151 | Nairobi | Alphamed Pharmacy | Nairobi | Private | Retail pharmacy |
| 152 | Nairobi | Kayole Pharmacy | Nairobi | Private | Retail pharmacy |
| 153 | Nairobi | Wabreiz Chemist | Nairobi | Private | Retail pharmacy |
| 154 | Nairobi | Githu Annex Chemist | Nairobi | Private | Retail pharmacy |
| 155 | Nairobi | Zapla B. Chemist | Nairobi | Private | Retail pharmacy |
| 156 | Nairobi | Pharmore Pharmacy Limited | Nairobi | Private | Retail pharmacy |
| 157 | Nairobi | Kenyatta National Hospital | Nairobi | Private | Hospital pharmacy |
| 158 | Nairobi | Mama Lucy Hospital | Nairobi | Private | Retail pharmacy |