

REPUBLIC OF KENYA



MINISTRY OF HEALTH

**REPORT ON RAPID RESULTS INITIATIVE OF POST MARKET
SURVEILLANCE OF SELECTED HEALTH PRODUCTS AND
HEALTH TECHNOLOGIES IN KENYA**

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Acknowledgements

This report presents the findings of a post market surveillance survey on selected health products and technologies carried out in collaboration between the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL) and the Kenya Medical Supplies Authority (KEMSA) under the auspices of a rapid results initiative (RRI) spearheaded by the Ministry of Health.

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Acronyms and Abbreviations

| | |
|----------|---|
| BP | British Pharmacopoeia |
| CoA | Certificate of Analysis |
| FDC | Fixed Dose Combination |
| FPP | Finished Pharmaceuticals Products |
| INN | International Non-Proprietary Name |
| ISO | International Standards Organization |
| KEMSA | Kenya Medical Supplies Authority |
| LMIC | Low- and Middle-Income Countries |
| MAH | Market Authorization Holder |
| MFL | Master Facility List |
| MOH | Ministry of Health |
| NMRA | National Medicines Regulatory Authority |
| NQCL | National Quality Control Laboratory |
| Ph. Int. | International Pharmacopoeia |
| PMS | Post Market Surveillance |
| PPB | Pharmacy and Poisons Board |
| RRI | Rapid Results Initiative |
| UHC | Universal Healthcare Coverage |
| USP | United States Pharmacopoeia |
| WHO | World Health Organization |

Definitions and 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 same 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 post market survey of selected health products and technologies was a collaborative study between the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL) and the Kenya Medical Supplies Authority (KEMSA), under the auspices of Ministry of Health, through a rapid results initiative approach. The survey targeted health products and technologies with high public health impact, and those that are widely used by the public. The products chosen were male latex condoms, syringes, antibiotics, analgesics, anti-hypertensive, anti-diabetics, anti-helminthic, contraceptives, hematinic and erectile dysfunction products.

The main objective of the survey was to assess the quality of selected health products and technologies circulating in the Kenyan market. Specifically to determine registration status, storage conditions at the site of collection and conduct laboratory analysis.

This was a descriptive cross-sectional survey that employed quantitative data collection methods. Products sampled were drawn from eleven (11) different active pharmaceutical ingredient (API) categories as well as two (2) medical device categories. The study covered both public and private health facilities including KEMSA main supply chain center, hospitals, distributors/wholesalers and retail pharmacies in seventeen (17) counties. The counties included the four pilot counties earmarked for universal healthcare coverage (UHC) rollout.

A total of 785 samples were collected, which represented 250 registrable products of which 215 (86%) were found to be registered.

The storage conditions of the products was analysed and 530 of the collected samples were found to be stored within manufacturers' recommended storage temperature conditions while 108 were found to be

stored in facilities where the recorded temperatures were outside the manufacturers' specifications. The remaining 147 samples did not have explicit manufacturers' storage specifications.

Two hundred and eighteen (218) out of the 243 secondary samples that were subjected to laboratory testing complied with all the test parameters evaluated. The number of pharmaceutical samples analysed was 203 while 40 were medical devices. Out of the 203 pharmaceutical product samples, 98.2% complied with the specifications for uniformity of weight; 92.6% complied with dissolution test requirements while 96.1% samples met specifications for content of active ingredient. All the samples complied with the test requirements for identification and pH (where applicable).

For medical devices, 90% complied with all the various test parameters evaluated while 5% did not meet at least one of the requirements for the dimensions tests and a further 5% failed to comply with specifications for the freedom from holes test.

1. INTRODUCTION

1.1 Background

Health products and technologies are essential component of healthcare service delivery. Essential medicines policies are crucial to promoting health and achieving sustainable development. These products must meet quality standards at their source and maintain the same throughout their shelf-lives in the market so as to effectively prevent and treat diseases. Further, access to quality health products and technologies by citizens increases public confidence in healthcare systems.

Ensuring quality of health products and technologies requires concerted efforts of all stakeholders in their entire lifecycle. A collaboration between the National Medicines Regulatory Authorities (NMRA), national procurement entities and the national medicines quality control laboratories represents a promising strategy towards the attainment of the Sustainable Development Goal of ensuring access to quality, safe, efficacious and effective health products and technologies.

1.2 Existing legal framework and government agencies

The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority established in 1957 by an Act of Parliament, the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya. PPB is charged with the responsibility of regulating the practice of pharmacy and trade in pharmaceuticals and related products. Its core mandate is to ensure the provision of quality, safe and efficacious medicinal substances. This is achieved through evaluation and registration of medicinal products, promotion of rational use of drugs, inspection and surveillance activities. It also includes licensing professionals and institutions, clinical trial authorization and advising the Government on any matter relating to regulation of medicines and related products.

The Kenya Medical Supplies Authority (KEMSA) was first established in 2000 as a state corporation through a legal notice under Cap. 466, Laws of Kenya. It is the Government body responsible for the procurement, warehousing and distribution of health products and technologies to public health institutions countrywide. The KEMSA Act of 2013 ratified the transformation of the Agency into a fully-fledged Authority under the new Constitution.

The National Quality Control Laboratory (NQCL) is the official medicines control laboratory and was established in 1992 through an amendment of the Pharmacy and Poisons Act, Cap. 244, Laws of Kenya. NQCL is the body mandated with carrying 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.

1.3 Universal Healthcare Coverage and the ‘Big Four Agenda’

In September 2015, the international community formally adopted the sustainable development goals with targets to end poverty, improve health, reduce inequality and address climate change globally by the year 2030. In Kenya the government has embarked on a development program for the period 2018-2022, termed the Big Four Agenda of which attainment of Universal Healthcare Coverage (UHC) has been earmarked as a principal pillar.

The concept of UHC embodies providing financial risk protection, improved access to quality essential healthcare services, medicines and vaccines for all to ensure attainment of improved health outcomes. Quality health products and technologies are a central component in attainment of UHC.

1.4 Problem Statement

According to the World Health Organization (WHO) it is estimated that 1 in 10 medical products circulating in low- and middle-income countries (LMICs) are either substandard or falsified. Since 2013,

WHO has received 1500 reports of cases of substandard or falsified products. Of these, anti-malarials and antibiotics are the most commonly reported. Most of the reports (42%) come from the WHO African Region, 21% from the WHO Region of the Americas, and 21% from the WHO European Region (1).

Prior to 2013, there was no global reporting of this information. Since WHO established the Global Surveillance and Monitoring System for substandard and falsified products, many countries are now active in reporting suspicious medicines, vaccines and medical devices. WHO has trained 550 regulators from 141 countries including Kenya, to detect and respond to substandard and falsified products.

WHO has received reports of substandard or falsified medical products ranging from anti-cancer treatment to contraceptives. They are not confined to high-value medicines or well-known brand names and are split almost evenly between generic and patented products (1). 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 (2).

The Kenya National Post Market Surveillance system was launched in 2009. Since then, Kenya has demonstrated a decline in the prevalence of poor-quality medicines over the period of 1997-2015 (3). The study shows a trend of decreasing poor-quality of medicines in the market from an average of 25% in 1997 to 4% in 2015. According to surveys on the quality of anti-malarials carried out between 2010-2016 in Kenya, there has been an increasing trend in the quality of medicines circulating in the market from 84% in 2010 to 96.4% in 2016 (4).

From the findings of these surveys it is evident that consistent post market surveillance activities are crucial in ensuring that quality, safe, efficacious and effective health products and technologies are in

the market.

1.5 Study Justification

Post market surveillance is an important tool in monitoring quality of health products and technologies post authorization. Poor quality products pose a major risk to public health and safety. This can be as a result of therapeutic failure which affects treatment outcomes and in turn leads to increased morbidity and mortality. In addition, poor treatment outcomes caused by poor quality medicines can lead to spurious reporting of resistance which leads to unwarranted change of treatment guidelines.

The detection of poor quality medical products in the market can lead to erosion of public confidence in healthcare systems which can further compromise the uptake of high public health priority, healthcare services such as immunization.

In the era of anti-microbial resistance, increase in resistance patterns has been associated with poor quality anti-microbial agents. The overall impact of these undesirable outcomes is wastage of resources. In view of the above, it is imperative that governments pursue the agenda of assuring quality of health products and technologies. One of the strategies to achieve this is through regular post-marketing surveillance.

Post-marketing surveillance activities entails routine surveys of health products and technologies circulating in the Kenyan market to assess their quality, safety, efficacy and effectiveness. In order to assess quality, samples are collected from the market and subjected to laboratory analysis and other evaluations.

The PPB in collaboration with NQCL and KEMSA set out to conduct a Rapid Results Initiative (RRI) within 100 days on quality of selected health products and technologies in the market. The RRI targeted

health products and technologies with high public health impact, and those that are widely used by the public. The products chosen included: male latex condoms, syringes, antibiotics, analgesics, anti-hypertensives, anti-diabetics, anti-helminthic, contraceptives, hematinics, erectile dysfunction products. These products are crucial in management of diseases of high public health impact. The study was intended to supplement routine and ongoing PMS activities for the quality of anti-retrovirals (ARVs), anti-tubercular agents, antimalarials and family planning commodities that have been carried out annually since 2015.

1.6 Main Objective

The main objective of this survey was to assess the quality of selected health products and technologies circulating in the Kenyan market.

1.7 Specific Objectives

1. To determine the registration status of sampled health products and technologies.
2. To assess the storage conditions of the sampled health products and technologies.
3. To carry out laboratory analysis of selected health products and technologies.

2 METHODOLOGY

2.1 Survey scope and duration

2.1.1 Geographical Area

This was a nationwide study that covered both public and private health facilities including KEMSA main supply chain center, hospitals, distributors/wholesalers and retail pharmacies in seventeen (17) counties. The counties included the four pilot counties earmarked for universal healthcare coverage (UHC) rollout.

2.1.2 Health products and technologies sampled

Products sampled were drawn from eleven (11) different active pharmaceutical ingredient (API) categories as well as two (2) medical device categories.

These products included: Albendazole tablets and suspensions; Amoxicillin capsules, dispersible tablets and dry suspensions; Ciprofloxacin tablets; Enalapril tablets; Folic acid tablets; Folic acid & Ferrous sulphate tablets (FDC); Glibenclamide tablets; Hydrochlorothiazide tablets; Levonorgestrel emergency contraceptives tablets; Metformin tablets; Paracetamol syrups/suspensions and tablets; and Sildenafil tablets (including herbal preparations claimed to be remedies for erectile dysfunction).

The medical devices comprised of male latex condoms and both 5 mL and 10 mL disposable manual use syringes.

Samples of condoms, levonorgestrel tablets and sildenafil were collected from private facilities only.

2.2 Survey Design

This was a descriptive cross-sectional survey that used quantitative data collection methods.

2.3 Sample Collection

A two-day training workshop for sample collectors was conducted that included a trial run of the data collection tools. The training was used to familiarize sample collectors with the requirements, expectations and data collection tools that were used in the survey.

Field work was carried out by 10 teams of up to 4 members each over a period of 15 days. In addition to data on medicine samples, temperature and humidity of the storage area at each sampling site were measured and recorded. The data were collected manually using the PMS sample collection form (Annex 1). The same data was captured in an Excel™ worksheet.

2.4 Sampling

A stratified purposive sampling strategy was applied to collect a primary pool of samples (P) from which a secondary sample (N) was drawn. The total number of the primary samples collected was 785 from which 243 (secondary) samples was drawn. The secondary samples in addition to all herbal erectile dysfunction (ED) products were submitted for laboratory analysis.

2.4.1 Sampling site facilities

The primary samples were collected from both public and private health facilities (Table 1).

In the private sector, samples were collected from purposively selected PPB registered distributors, wholesalers and high-volume retail pharmacies in the following urban areas: Eldoret, Garissa, Kisumu, Mombasa, Nairobi, Nakuru, Isiolo, Nyeri, Embu and Kajiado. Pharmaceutical wholesalers, distributors and high-volume retail pharmacies were selected on the expectation that they would greatly increase the odds of collecting products from the widest variety of manufacturers as well as stocking adequate quantities for

sampling. Furthermore, it would be expected that the majority of retail outlets source their commodities from these pharmaceuticals' wholesalers.

Table 1: List of sampling site facilities

| | County | Public Health Facility | Private Facility |
|-----|---------------|---|----------------------------------|
| 1. | Nairobi | KEMSA main supply chain centre | Generics Africa |
| | | Kenyatta National Hospital | Harleys Pharmaceuticals |
| | | | Nila Pharmaceuticals |
| | | | Rafiki Pharmaceuticals |
| | | | Surgipharm Ltd |
| | | | Transchem |
| | | | Zen Pharmaceuticals - Prestige |
| 2. | Kisumu | Jaramogi Oginga Odinga Teaching & Referral Hospital | Kentons Ltd |
| | | Kisumu County Hospital | Laborex |
| | | Muhoroni County Hospital | Victoria Healthcare |
| | | Ahero County Hospital | |
| 3. | Machakos | Machakos Level 5 Hospital | Bishop Kioko Catholic Hospital |
| | | Kangundo District Hospital | |
| | | Athi River Health Centre | |
| 4. | Isiolo | Isiolo District Hospital | Daima Pharmacy |
| | | Kinna Health Centre | Sage Pharmacy |
| | | | Matercare Maternity Hospital |
| 5. | Nyeri | Nyeri Provincial General Hospital | Outspan Hospital |
| | | Karatina District Hospital | |
| | | Mukurweini District Hospital | |
| 6. | Garissa | | Afya Centre |
| | | | Al-Qudus Pharmaceuticals |
| | | | Makkah Pharmaceuticals Ltd |
| | | | Medina Pharmacy Limited |
| | | | Ummah Pharmacy |
| 7. | Mombasa | | Eldohosp Pharmaceuticals Mombasa |
| | | | Makadara Chemist |
| | | | Shifa Chemist |
| | | | Surgipharm Ltd Mombasa |
| 8. | Uasin Gishu | | Eldohosp Pharmaceuticals |
| | | | Lifecare Pharmaceuticals |
| | | | Northpharm Company Limited |
| | | | Pilot Pharmaceuticals |
| 9. | Kilifi | | Azmon Pharmacy |
| | | | Old Madaraka Chemist |
| | | | Reenland Pharmacy |
| | | | Sabaki Pharmacy |
| 10. | Embu | | Itabua Chemist |
| | | | Mbeti Pharmacy |
| | | | T. D Concept |
| 11. | Kajiado | | Hartlane Pharmaceuticals Ltd |
| | | | Lenana Pharmaceuticals Ltd |

| | County | Public Health Facility | Private Facility |
|-----|---------------|-------------------------------|--|
| 12. | Kitui | | Nunguni Chemists Ltd Snow Pharmacy Stera Pharmacy |
| 13. | Meru | Meru District Hospital | St Theresa Kiirua Hospital (Kiirua) |
| 14. | Trans Nzoia | | Sarara Chemist |
| 15. | Nakuru | | Elim Central Pharmacy Supreme Pharmacy Transwide Pharmaceuticals |
| 16. | Narok | | Agape Pharmaceuticals Jaslim Pharmacy Nenkai Pharmaceutical Stores |
| 17. | Busia | | Scorpion Pharmacy |

Facilities details were captured in facility form (Annex 2).

2.4.2 Primary sampling procedure

A minimum quantity of 50 tablets/capsules for oral solid formulations and 10 bottles for oral liquid formulations were sampled. For male latex condoms, a minimum sample size of 1,000 units and a minimum sample of 50 units for syringes, were sampled. Only products with more than six months of shelf life were sampled. The minimum quantity of health products and technologies sampled and the tests that were carried out are illustrated in (Annex 3).

The primary sample size was based on the following considerations:

- i. The timeframe for completion of the PMS exercise (70/100 days allocated for sample analysis).
- ii. The annual consumption data obtained from KEMSA, medicines import data from ports of entry and the number of unique product brands registered and retained for the year 2017, was weighted to ensure proportionate selection of the secondary samples to be analyzed.

The procedure for collecting primary samples was as follows:

- i. An overt approach was applied in the sample collection whereby, the sample collectors introduced themselves to the facilities indicating the objectives of the survey. However, covert approach

was used to obtain some of the herbal ED products.

- ii. Products were sampled from either the bulk store or the dispensing area by the sample collectors as per the primary sample matrix (Table 2)
- iii. Each sample was appropriately labeled using the formulation codes (Annex 4), packed individually and accompanied with a duly filled out *Sample Collection Form* (Annex 1) in an envelope. Details of the site of collection were captured in the appropriate *Facility Form* (Annex 2).
- iv. Information from the sample collection form was entered into an Excel PMS sample aggregation worksheet before packing the samples in designated boxes.
- v. The collected samples were then packed in separate boxes, labelled (team number, category of medicine and date packed) and dispatched to the Pharmacy and Poisons Board Headquarters.
- vi. Sample integrity was safeguarded by ensuring that all samples were collected in their original, sealed, clearly labeled container. This was maintained until delivery of the products for laboratory testing.

The following were the proposed number of samples (*P*) to be collected at the different survey sites (Table 2)

Table 2: The number of primary samples to be collected

| Sites | | ALB | AMX | CPR | ENP | FAF | GLB | HCT | LNG | MTF | PCM | SDF | CDM | SYR |
|---------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Private | Eldoret | 4 | 8 | 4 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2 | 4 | 2 |
| | Trans-Nzoia | 2 | 4 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 2 | 1 |
| | Garissa | 4 | 8 | 4 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2 | 4 | 2 |
| | Kitui | 2 | 4 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 2 | 1 |
| | Kisumu | 2 | 4 | 2 | 2 | 2 | 2 | 2 | 4 | 2 | 4 | 4 | 4 | 4 |
| | Busia | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 2 | 2 | 2 | 2 |
| | Mombasa | 4 | 8 | 6 | 2 | 2 | 2 | 2 | 6 | 2 | 8 | 4 | 6 | 6 |
| | Kilifi | 2 | 4 | 3 | 1 | 1 | 1 | 1 | 3 | 1 | 4 | 2 | 3 | 3 |
| | Nairobi | 6 | 15 | 9 | 6 | 3 | 6 | 6 | 12 | 6 | 12 | 9 | 12 | 12 |
| | Nakuru | 4 | 8 | 4 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 4 | 2 | 4 |
| | Narok | 2 | 4 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 2 | 1 | 2 |
| Public | Isiolo | 4 | 8 | 4 | 2 | 2 | 2 | 4 | 0 | 2 | 6 | 0 | 0 | 4 |

| Sites | ALB | AMX | CPR | ENP | FAF | GLB | HCT | LNG | MTF | PCM | SDF | CDM | SYR |
|--------------------|------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Meru | 2 | 4 | 2 | 1 | 1 | 1 | 2 | 0 | 1 | 3 | 0 | 0 | 2 |
| Kisumu | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 6 | 0 | 0 | 9 |
| Machakos | 4 | 8 | 4 | 2 | 2 | 2 | 4 | 0 | 2 | 6 | 0 | 0 | 4 |
| Kajiado | 2 | 4 | 2 | 1 | 1 | 1 | 2 | 0 | 1 | 3 | 0 | 0 | 2 |
| Nyeri | 2 | 8 | 4 | 4 | 2 | 4 | 4 | 0 | 4 | 9 | 0 | 0 | 4 |
| Embu | 1 | 4 | 2 | 2 | 1 | 2 | 2 | 0 | 2 | 3 | 0 | 0 | 2 |
| KEMSA | 6 | 12 | 6 | 3 | 3 | 3 | 3 | 0 | 3 | 9 | 0 | 0 | 12 |
| Sub-Totals | 57 | 123 | 66 | 39 | 33 | 39 | 45 | 36 | 39 | 99 | 33 | 42 | 78 |
| GRAND TOTAL | 729 | | | | | | | | | | | | |

ALB =Albendazole, AMX = Amoxicillin, CPR = Ciprofoxacin, ENP = Enalapril, FA=Folic acid, FAF = folic acid & Ferrous sulphae, GLB = Glibenclamide, HCT = Hydrochlorthiazide, LNG = Levonorgestrel, MTF = Metformin, PCM = Paracetamol, SDF = Sildenafil, CDM = Male latex condoms and SYR = Syringes

2.4.3 Secondary sampling

The individual samples were selected using random sampling. Random numbers were generated using MS-Excel with stratification to ensure proportionate representation of samples from all the 17 counties sampled. Secondary sampling approach ensures optimization of resources and achieves generalization of the findings.

This is as summarized in the sampling matrix as shown in Table 3.

Table 3: Secondary Sampling Matrix

| Sites | ALB | AMX | CPR | ENP | FAF | GLB | HCT | LNG | MTF | PCM | SDF | CDM | SYR | |
|---------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|---|
| Private | Eldoret | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | |
| | Trans-Nzoia | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | |
| | Garissa | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | |
| | Kitui | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | |
| | Kisumu | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | Busia | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | Mombasa | 1 | 3 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | 3 | 1 | 2 | 2 |
| | Kilifi | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 1 |
| | Nairobi | 2 | 5 | 3 | 2 | 1 | 2 | 2 | 4 | 2 | 4 | 3 | 4 | 4 |
| | Nakuru | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 |
| Narok | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | |
| Public | Isiolo | 1 | 3 | 1 | 1 | 1 | 1 | 0 | 1 | 2 | 0 | 0 | 1 | |
| | Meru | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 1 | |
| | Kisumu | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 2 | 0 | 3 | |
| | Machakos | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 2 | 0 | 1 | |
| | Kajiado | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | |

| Sites | ALB | AMX | CPR | ENP | FAF | GLB | HCT | LNG | MTF | PCM | SDF | CDM | SYR |
|--------------------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Nyeri | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 2 | 0 | 0 | 1 |
| Embu | 0 | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 |
| KEMSA | 2 | 4 | 2 | 1 | 1 | 1 | 1 | 0 | 1 | 3 | 0 | 0 | 4 |
| Sub-Totals | 19 | 41 | 22 | 13 | 11 | 13 | 15 | 12 | 13 | 33 | 11 | 14 | 26 |
| GRAND TOTAL | 243 | | | | | | | | | | | | |

ALB = Albendazole, AMX = Amoxicillin, CDM = Male latex condom CPR = Ciprofoxacin, ENP = Enalapril, FA = Folic acid, FAF = Folic acid & Ferrous sulphate, GLB = Glibenclamide, HCT = Hydrochlorthiazide, LNG = Levonorgestrel, MTF = Metformin, PCM = Paracetamol, SDF = Sildenafil, SYR = Syringes

2.5 Laboratory Analysis

A total of two hundred and forty-three (243) health products and technologies were submitted to the Laboratory for analysis.

An analysis request form was filled for each of the samples selected for laboratory analysis following the secondary sampling exercise. Tablet formulations were subjected to weight uniformity, identification, assay and dissolution tests while liquid formulations were subjected to identification, pH determination and assay tests. The male latex condoms were subjected to air inflation, freedom from holes and dimensions tests while the manual use syringes were subjected to plunger function and pH tests.

2.5.1 Compendia Used

Official and non-official compendia were used in the analysis of the samples as listed below:

- i. British Pharmacopoeia (BP), 2017, The Stationery Office, London.
- ii. United States Pharmacopoeia 41 National Formulary 36, (2018), The United States Pharmacopoeial Convention, Washington D.C.
- iii. The International Pharmacopoeia, 7th Edition, 2017, World Health Organization.
- iv. ISO 7886-1:2017: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use.
- v. ISO 4074:2015: Natural rubber latex male condoms - Requirements and test methods.

vi. Manufacturer's In-House Method.

Test procedures and compliance limits for individual product samples were described in detail in the monographs in the above compendia.

2.5.2 Reagents and Solvents

All chemicals, reagents and solvents used were of the highest purity as specified in the compendia listed above.

2.5.3 Chemical Reference Standards

Primary chemical reference substances obtained from the United States Pharmacopoeia, Rockville, Maryland, USA or working chemical reference substances traceable to a primary chemical reference substance were used in the quantitative tests.

2.5.4 Instrumentation

All testing equipment used were qualified and deemed appropriate for the tests performed as per the internal standard operating procedures.

2.5.5 Sample Preparation

The sample and chemical reference standard solutions were prepared as outlined in the test monographs contained in the appropriate compendia listed above.

2.5.6 Analytical Tests

2.5.6.1 Acidity/Alkalinity

This is a measure of the pH of the sample. This was performed for all samples in liquid dosage form. The test involves taking an appropriate volume of sample and reading its pH using a pH meter. The observed value is compared against the limits specified in the appropriate monograph. pH is an important parameter that influences the chemical stability of most pharmaceutical products.

2.5.6.2 Dissolution

The dissolution test is carried out as a means of determining the *in vitro* release of active ingredients in the tablet and capsule formulations in a specified medium maintained at 37 ± 2 °C over a specified duration under carefully regulated conditions of pH and agitation as specified in the appropriate monograph.

Six dosage units are run individually in the dissolution tester and the amount dissolved as a percentage of the stated amount determined using an appropriate quantification procedure as specified in the appropriate monograph. The pharmacopeia provides for three stages of testing with increasing sample size and decreasing specifications. Stage one (S1) test specification for the sample requires 6 units where none should be less than Q+5%. If a sample fails S1 you progress to S2 in which case the sample size increases to 12 units and limits change; the average of the 12 units should not be less than Q% and no single unit should be less than Q-15%. The value for Q is defined in specific monographs.

2.5.6.3 Assay

This involves the determination of the amount of active ingredient in a pharmaceutical preparation expressed as a percentage of the labelled amount. The sample and chemical reference substance preparation, the testing parameters and instrumentation are specified in the appropriate monograph. In all cases regardless of the analytical technique used (HPLC, UV spectroscopy), sample solutions were freshly prepared in triplicate and reference standard solutions in duplicate. Replicate determinations of both test sample and reference standard solutions were made concurrently. Any repeat tests were done using freshly prepared solutions.

The amount of active ingredient in the sample is determined by comparing the response due to the sample solution against the response of the chemical reference substance solution whose concentration is known. This is stated as a percentage of the labelled amount and compared against the

limits specified in the appropriate monograph.

2.5.6.4 Force to Operate Syringe Piston

This is a test performed on manual use syringes that involves the determination of the force applied to initiate the initial movement of the plunger in the barrel of the syringe, the average force applied during the plunger travel and the maximum force at any time during the travel. This is determined for ten syringes and average forces determined are recorded.

2.5.6.5 Burst Volume and Pressure

A total of 315 condoms per test sample are individually filled with compressed air from an automated air inflation system and at the point of breakage of the condom, the fill volume and pressures achieved are recorded. The burst volume and pressure provide an indication of the mechanical strength of latex condoms.

2.5.6.6 Dimensions

Measurements taken include length, width and thickness of an individual condom. This is determined for 13 condoms using an automated dimensions tester which calculates the mean, maximum and minimum values for each dimension tested.

2.5.6.7 Freedom from Holes

This test is carried out to determine the presence of holes in the condom. The condom is filled with an electrolyte solution and then dipped in a bath of a similar electrolyte solution. The condom itself acts as an insulator, separating the two solutions. If there is a hole in the condom, the insulation is broken and an electric current will flow between the solution in the condom and the solution in the bath. This is determined for 315 condoms.

2.5.7 Reporting of test results and out of specification procedures.

A Certificate of Analysis (CoA) incorporating a summary of the actual method used to test each sample and the results obtained was issued for each of the 243 samples analyzed. Any sample that failed to comply with any of the above tests was subjected to a comprehensive out of specification (OOS) investigative procedure before release of the final results.

3 RESULTS AND DISCUSSION

3.1 Primary sample description

The total number of samples collected was 785 out of the intended sample size of 729, giving us a 107% collection. These were made up of 271 different brands (Table 4).

Table 4: Description of the primary samples collected

| APIs | Planned | Collected | % | *Product diversity in market (no.) |
|---------------------|------------|------------|--------------|------------------------------------|
| Albendazole | 57 | 62 | 108.8 | 26 |
| Amoxicillin | 123 | 120 | 97.6 | 32 |
| Ciprofloxacin | 66 | 72 | 109.1 | 25 |
| Condom | 42 | 34 | 81.0 | 17 |
| Enalapril | 39 | 44 | 112.8 | 17 |
| Folic acid | 16 | 29 | 181.3 | 9 |
| Folic/Ferrous | 17 | 18 | 105.9 | 3 |
| Glibenclamide | 39 | 37 | 94.9 | 5 |
| Herbal ED | | 29 | | 21 |
| Hydrochlorothiazide | 45 | 41 | 91.1 | 3 |
| Levonorgestrel | 36 | 30 | 83.3 | 13 |
| Metformin | 39 | 45 | 115.4 | 14 |
| Paracetamol | 99 | 107 | 108.1 | 34 |
| Sildenafil | 33 | 36 | 109.1 | 24 |
| Syringes | 78 | 81 | 103.8 | 28 |
| Grand Total | 729 | 785 | 107.7 | 271 |

The samples collected comprised of innovator products, generic products, herbal preparations and medical devices as shown below with 71.2% being generic pharmaceutical products (Figure 2).

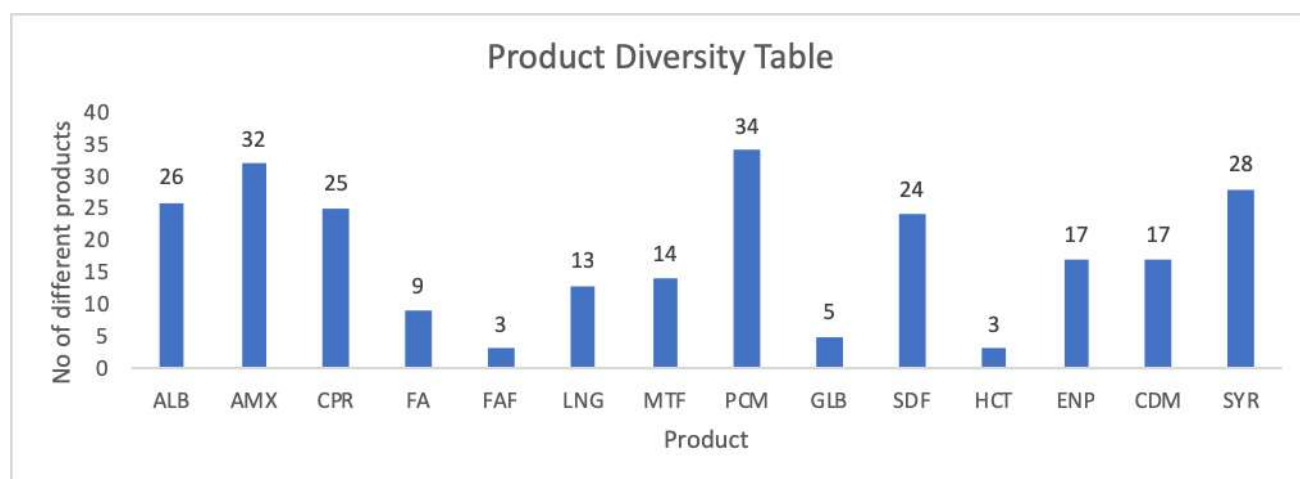


Figure 1: Product diversity table

ALB =Albendazole, AMX = Amoxicillin, CDM = Male latex condom, CPR = Ciprofoxacin, ENP = Enalapril, FA = Folic acid, FAF = Folic acid & Ferrous sulphate, GLB = Glibenclamide, HCT = Hydrochlorothiazide, LNG = Levonorgestrel, MTF = Metformin, PCM = Paracetamol, SDF = Sildenafil, SYR =Syringes

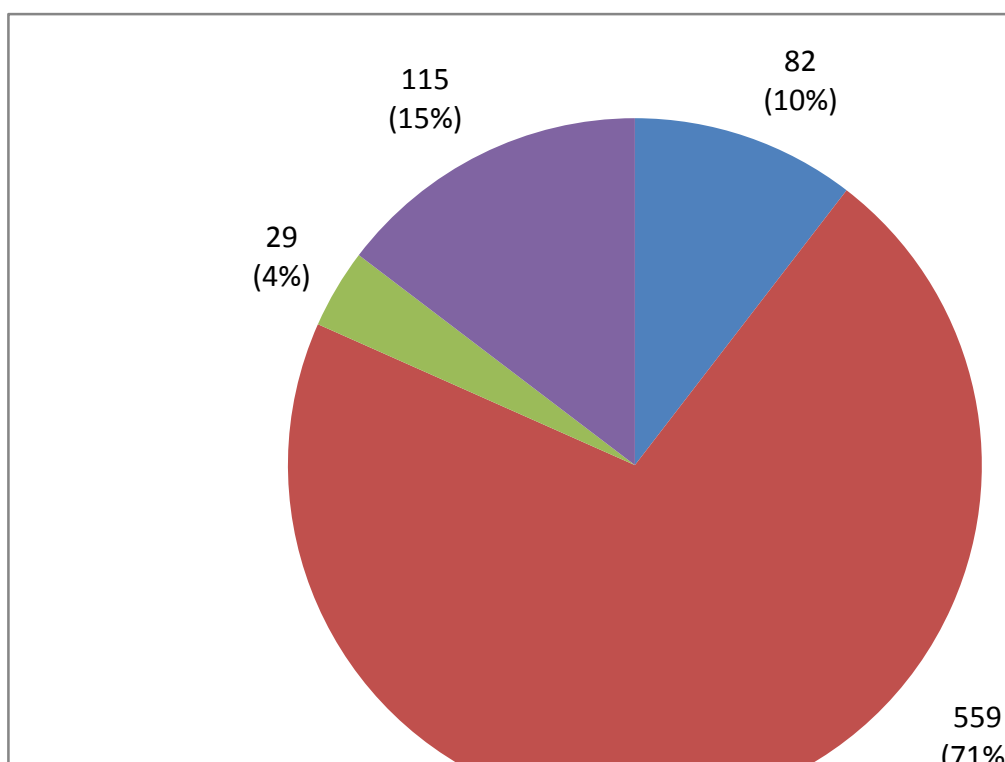


Figure 2: Pie chart of products collected

In terms of sample collection by sector, of the total 785 samples collected, 544 (69.2%) were from the private sector, 205 (26.1%) from the public sector and 36 (4.6%) from faith based organizations as indicated below.

Table 5: Samples collected by sector

| Primary sample | Faith-Based | Private | Public | Total |
|------------------------------------|-------------|---------|--------|-------|
| Albendazole | 5 | 42 | 15 | 62 |
| Amoxicillin | 7 | 85 | 28 | 120 |
| Ciprofloxacin | 4 | 50 | 18 | 72 |
| Condom | 0 | 34 | 0 | 34 |
| Enalapril | 2 | 30 | 12 | 44 |
| Folic acid | 2 | 17 | 10 | 29 |
| Folic acid/Ferrous sulphate | 1 | 4 | 13 | 18 |
| Glibenclamide | 1 | 23 | 13 | 37 |
| Herbal ED | 0 | 29 | 0 | 29 |
| Hydrochlorothiazide | 2 | 23 | 16 | 41 |
| Levonorgestrel | 0 | 30 | 0 | 30 |
| Metformin | 3 | 28 | 14 | 45 |
| Paracetamol | 4 | 70 | 33 | 107 |
| Sildenafil | 0 | 36 | 0 | 36 |

| | | | | |
|--------------------|-----------|------------|------------|------------|
| Syringes | 5 | 43 | 33 | 81 |
| Grand Total | 36 | 544 | 205 | 785 |

The number of primary samples (P) collected at the different survey sites in various counties are as shown in Table 6 and Figure 3.

Table 6: Matrix of primary samples collected in various counties.

| County | | ALB | AMX | CPR | CDM | ENP | FA | FAF | GLB | Herbal ED | HCT | LNG | MTF | PCM | SDF | SYR | Total |
|--------------------|--------------------|-----------|------------|-----------|-----------|-----------|-----------|-----------|-----------|--------------|-----------|-----------|-----------|------------|-----------|-----------|------------|
| Private | Busia | 2 | 2 | 1 | 0 | 2 | 1 | 0 | 1 | 1 | 1 | 2 | 1 | 2 | 2 | 2 | 20 |
| | Embu | 2 | 5 | 3 | 0 | 3 | 2 | 0 | 2 | 0 | 1 | 0 | 4 | 5 | 0 | 3 | 30 |
| | Garissa | 4 | 6 | 4 | 0 | 4 | 2 | 0 | 1 | 3 | 2 | 1 | 2 | 6 | 2 | 2 | 39 |
| | Isiolo | 4 | 4 | 2 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 2 | 1 | 0 | 2 | 18 |
| | Kajiado | 1 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 4 | 0 | 0 | 14 |
| | Kilifi | 0 | 7 | 3 | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 5 | 5 | 3 | 30 |
| | Kisumu | 5 | 6 | 4 | 4 | 2 | 1 | 0 | 2 | 0 | 2 | 1 | 5 | 6 | 4 | 5 | 47 |
| | Kitui | 2 | 5 | 3 | 3 | 3 | 1 | 0 | 2 | 0 | 1 | 1 | 1 | 5 | 3 | 1 | 31 |
| | Machakos | 2 | 2 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 2 | 0 | 1 | 12 |
| | Meru | 1 | 2 | 2 | 0 | 1 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 2 | 0 | 2 | 14 |
| | Mombasa | 5 | 8 | 6 | 9 | 1 | 2 | 0 | 2 | 1 | 2 | 6 | 2 | 8 | 3 | 6 | 61 |
| | Nairobi | 7 | 19 | 7 | 9 | 6 | 2 | 1 | 4 | 17 | 3 | 10 | 6 | 11 | 8 | 11 | 121 |
| | Nakuru | 4 | 7 | 5 | 2 | 2 | 2 | 1 | 2 | 3 | 2 | 2 | 2 | 5 | 4 | 4 | 47 |
| | Narok | 2 | 4 | 3 | 0 | 1 | 0 | 1 | 1 | 0 | 1 | 2 | 0 | 4 | 2 | 3 | 24 |
| | Nyeri | 0 | 1 | 1 | 0 | 2 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 |
| | Trans Nzoia | 1 | 3 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 14 |
| Uasin-Gishu | 5 | 8 | 5 | 6 | 3 | 2 | 1 | 3 | 3 | 2 | 2 | 2 | 6 | 2 | 2 | 52 | |
| Public | Isiolo | 2 | 5 | 2 | 0 | 1 | 2 | 2 | 3 | 0 | 2 | 0 | 1 | 6 | 0 | 4 | 30 |
| | Kisumu | 1 | 5 | 2 | 0 | 2 | 2 | 3 | 3 | 0 | 3 | 0 | 1 | 6 | 0 | 8 | 36 |
| | Machakos | 3 | 7 | 2 | 0 | 3 | 2 | 2 | 3 | 0 | 2 | 0 | 2 | 4 | 0 | 5 | 35 |
| | Meru | 1 | 1 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0 | 2 | 10 |
| | Nairobi | 6 | 4 | 7 | 0 | 4 | 0 | 3 | 3 | 0 | 4 | 0 | 5 | 9 | 0 | 8 | 53 |
| Nyeri | 2 | 6 | 4 | 0 | 2 | 2 | 3 | 1 | 0 | 4 | 0 | 5 | 6 | 0 | 6 | 41 | |
| Totals | | 62 | 120 | 72 | 34 | 44 | 29 | 18 | 37 | 29 | 41 | 30 | 45 | 107 | 36 | 81 | 785 |

ALB =Albendazole, AMX = Amoxicillin, CPR = Ciprofoxacin, ENP = Enalapril, FA=Folic acid, FAF = folic acid & Ferrous sulphate, GLB = Glibenclamide, HCT = Hydrochlorthiazide, LNG = Levonorgestrel, MTF = Metformin, PCM = Paracetamol, SDF = Sildenafil, CDM = Male latex condoms and SYR = Syringes

The majority of samples collected were from Nairobi (174), followed by Kisumu (83), Mombasa (61) while Trans-Nzoia and Kajiado had the least number of samples at 14 each.

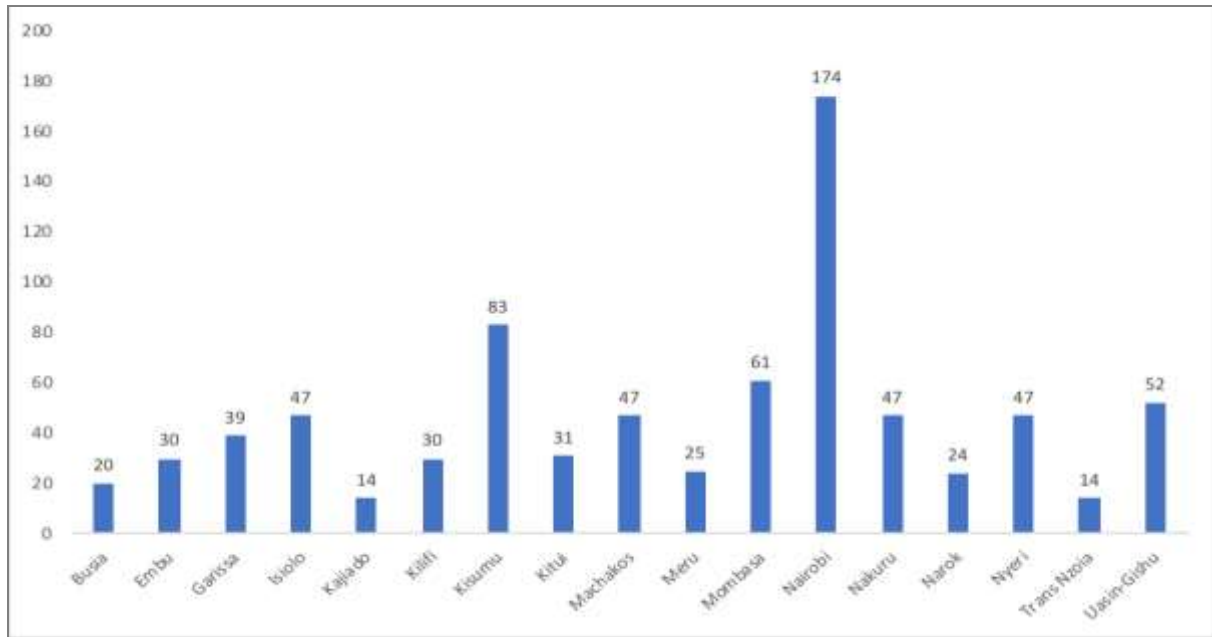


Figure 3: Graphical representation of number of primary samples by county

Figure 4 shows samples collected from various facilities, namely: wholesalers (364); retailers (155); county hospitals (73) and sub-district/county hospitals (7).

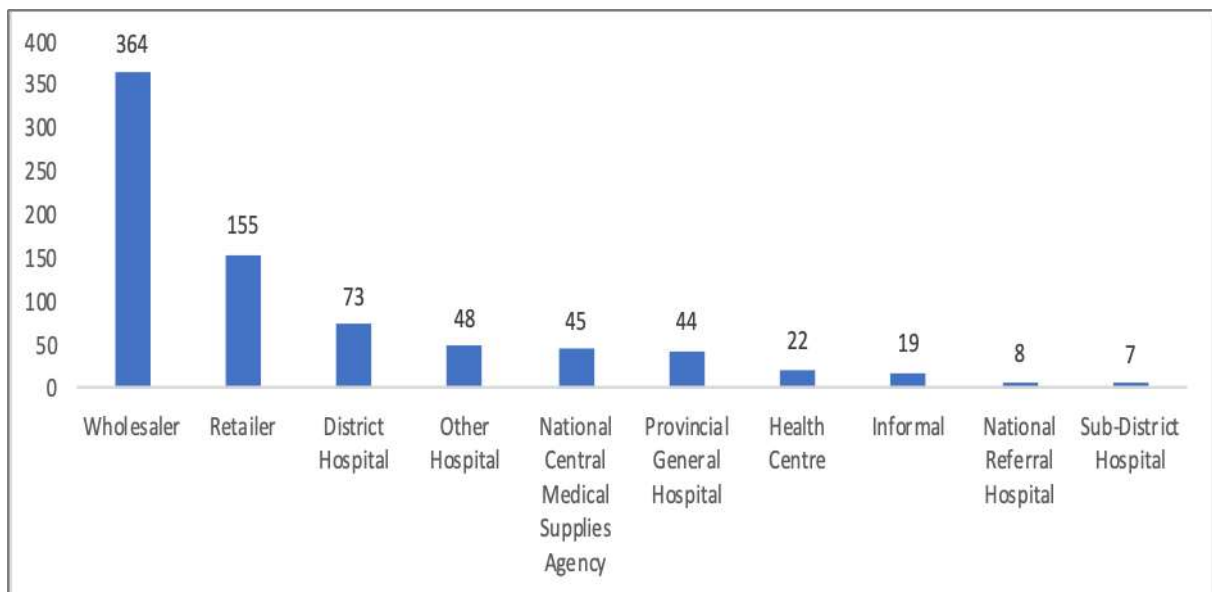


Figure 4: Samples collected by facility type

Figure 5 shows the formulations of pharmaceuticals and other health technologies collected. Of these products, tablets (58.5%) were the majority followed by oral suspensions (14.1%) while soft gel capsules were the least (0.3%).

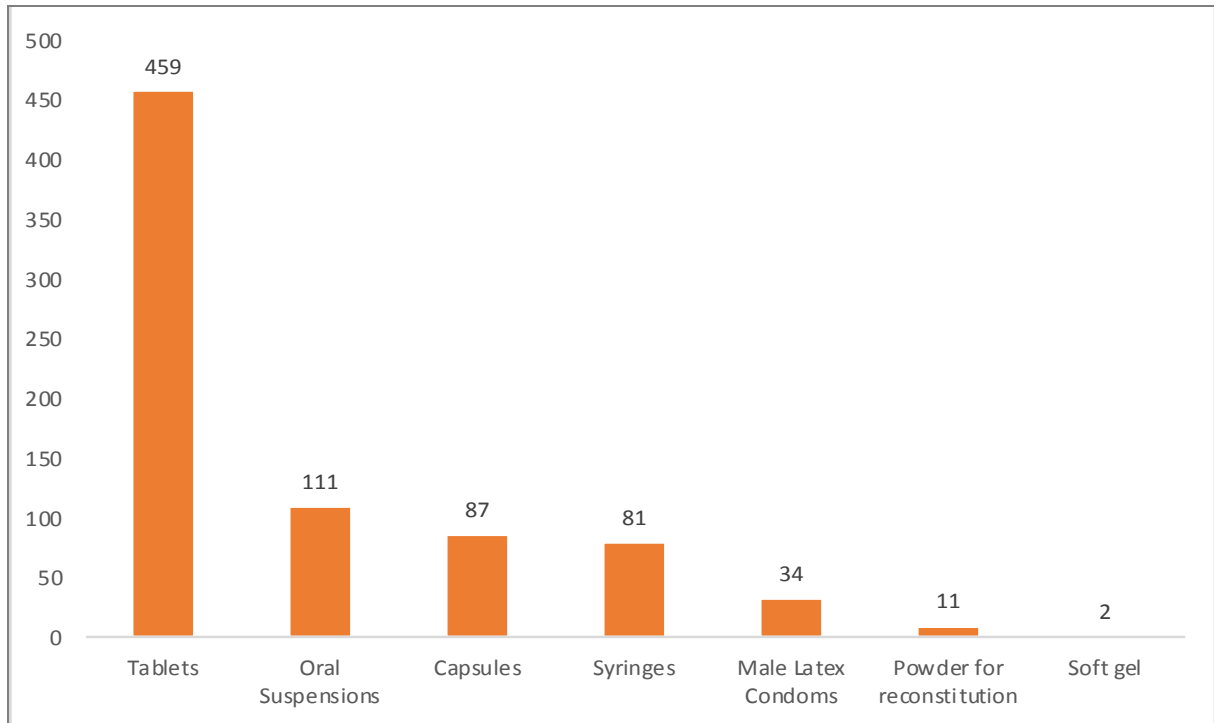


Figure 5: Number of sample formulations

3.2 Registration Status

3.2.1 Registration status of primary samples

Table 7: Registration Status of Primary Samples

| S/No | INN Name | No Sampled | No of products | Registered | Products not registered | % not registered |
|------|---------------------|------------|----------------|------------|-------------------------|------------------|
| 1. | Albendazole | 61 | 26 | 24 | 2 | 7.7 |
| 2. | Amoxicillin | 120 | 32 | 29 | 3 | 9.4 |
| 3. | Ciprofloxacin | 72 | 25 | 24 | 1 | 4.0 |
| 4. | Folic Acid | 29 | 9 | 5 | 4 | 44.0 |
| 5. | Folic Acid & Fe | 18 | 3 | 2 | 1 | 33.0 |
| 6. | Levonorgestrel | 30 | 13 | 12 | 1 | 7.7 |
| 7. | Metformin | 45 | 14 | 13 | 1 | 7.0 |
| 8. | Paracetamol | 108 | 34 | 33 | 1 | 3.0 |
| 9. | Glibenclamide | 37 | 5 | 5 | 0 | 0 |
| 10. | Sildenafil | 36 | 24 | 24 | 0 | 0 |
| 11. | Hydrochlorothiazide | 41 | 3 | 3 | 0 | 0 |
| 12. | Enalapril | 44 | 17 | 17 | 0 | 0 |
| 13. | Male Latex Condoms | 34 | 17 | 11 | 6 | 35.3 |
| 14. | Syringes | 81 | 28 | 13 | 15 | 53.6 |
| | Total | 756 | 250 | 215 | 35 | 14.0 |

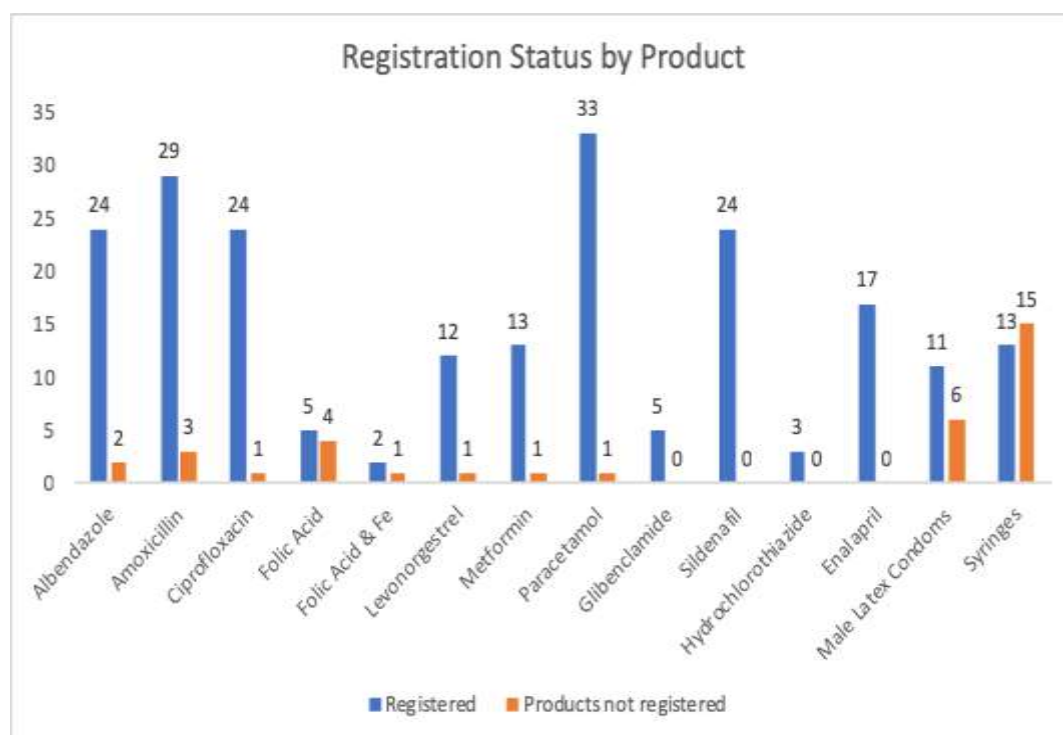


Figure 6: Registration status by product

The total number of pharmaceutical products were 205 of which 14 (6.8%) were not registered. For the 45 medical devices, 6 out of 17 male latex

condoms (35.3%) and 15 out of 28 syringes (53.6%) were not registered.

The high rate of unregistered medical devices might be attributable to the fact that these products were initially being regulated by multiple agencies.

3.2.2 Registration status of secondary samples

Table 8: Registration Status of Secondary Samples

| S/No | INN Name | No Sampled for Lab | No of products | Registered | Products Not Registered |
|--------------|---------------------|--------------------|----------------|------------|-------------------------|
| 1. | Albendazole | 19 | 14 | 14 | 0 |
| 2. | Amoxicillin | 40 | 27 | 25 | 2 |
| 3. | Ciprofloxacin | 21 | 18 | 18 | 0 |
| 4. | Folic Acid | 7 | 7 | 5 | 2 |
| 5. | Folic Acid & Fe | 5 | 2 | 1 | 1 |
| 6. | Levonorgestrel | 12 | 11 | 10 | 1 |
| 7. | Metformin | 14 | 12 | 11 | 1 |
| 8. | Paracetamol | 33 | 23 | 22 | 1 |
| 9. | Glibenclamide | 13 | 5 | 5 | 0 |
| 10. | Sildenafil | 11 | 11 | 11 | 0 |
| 11. | Hydrochlorothiazide | 15 | 3 | 3 | 0 |
| 12. | Enalapril | 13 | 11 | 11 | 0 |
| 13. | Male Latex Condoms | 14 | 11 | 9 | 2 |
| 14. | Syringes | 26 | 17 | 11 | 6 |
| Total | | 243 | 172 | 156 | 16 |

The total number of pharmaceutical products taken to the laboratory for analysis were 144 of which 136 (94.4%) were registered while 8 (5.6%) were unregistered.

The total number of medical device products taken for analysis were 28 of which 20 (71.4%) were registered while 8 (28.6%) were unregistered.

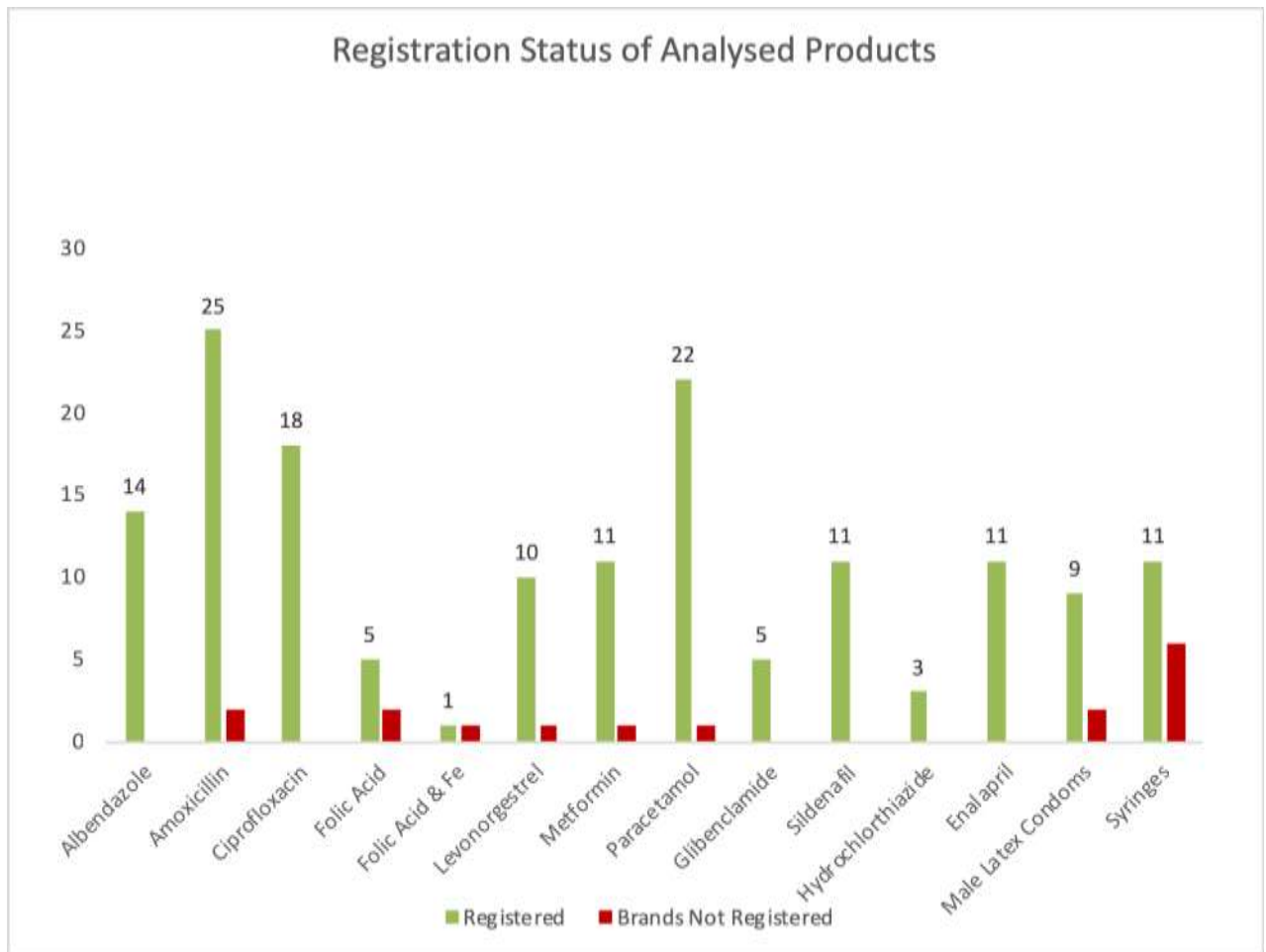


Figure 7: Registration status of analyzed products

3.3 Storage Conditions

Field teams that collected samples from different facilities were tasked with recording the ambient temperatures and relative humidity conditions at the time of sample collection. This data was collected using calibrated digital thermo-hygrometers (Electronic Weather station model 13/420/0, Brannan Thermometers & Instrumentation, Cambria, UK) and recorded in the appropriate facility detail forms (Annex 2).

3.3.1 Recorded Facility Temperatures and Humidity

Temperature and humidity data were collected from a total of 64 different facilities. A total of 785 samples were collected from these sites. 353 samples (45%) were collected from facilities where the recorded temperature was below 25 °C while 367 samples (47%) were collected from sites where temperatures ranged from 25 °C to 30 °C. The remaining 65 samples were stored at temperatures above 30 °C (Figure 8).

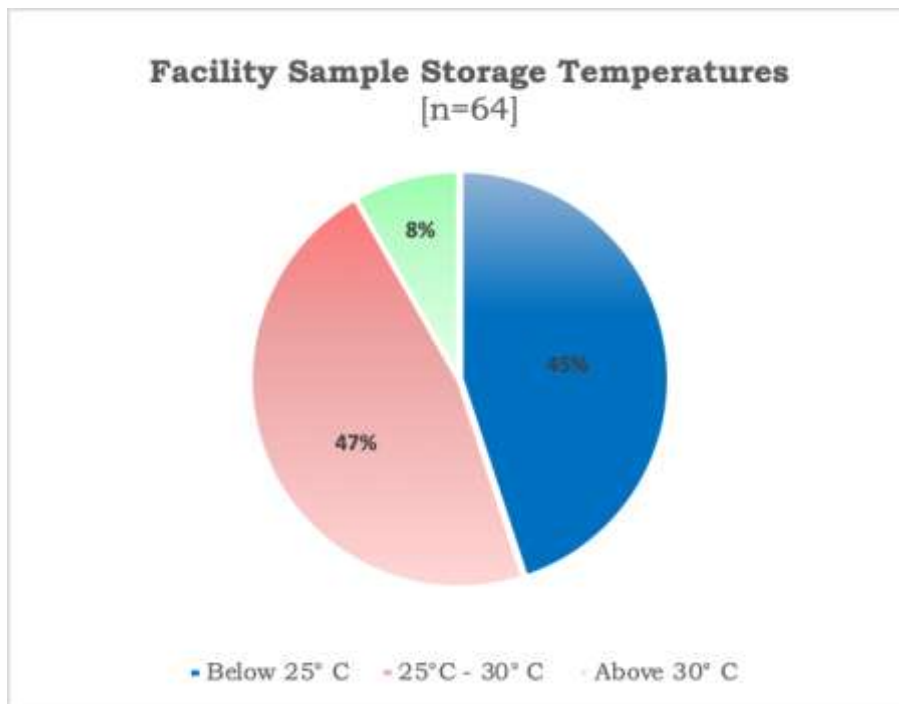


Figure 8: Facility sample storage temperatures

Temperatures recorded at the facilities from which samples were collected ranged from a low of 19.9 °C (Karatina District Hospital, Nyeri) to a high of 37.1 °C (Afya Centre, Garissa). In the majority (94%) of sites, however, the ambient temperature at the time of sample collection ranged between 20 – 32 °C as illustrated in Figure 9

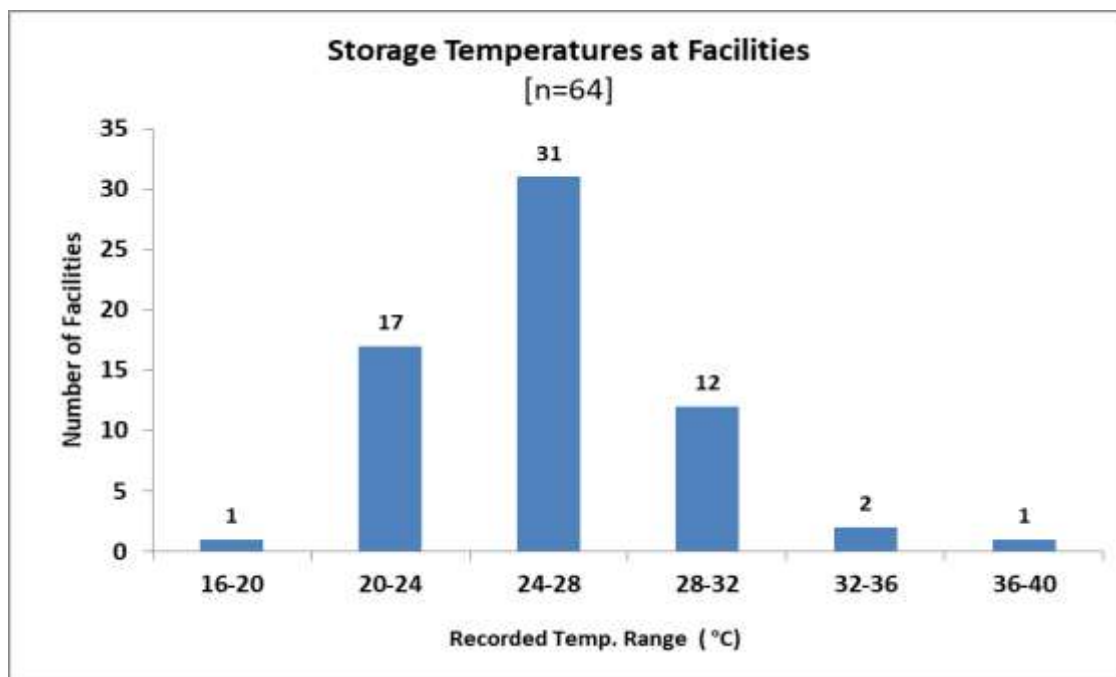


Figure 9: Storage temperature ranges at sampled facilities

Relative humidity values recorded at the sites of sample collection were found to range from 33% to 78%. The frequency distribution of the relative humidity values recorded in all the 64 facilities from which samples were collected is illustrated in Figure 10 below.

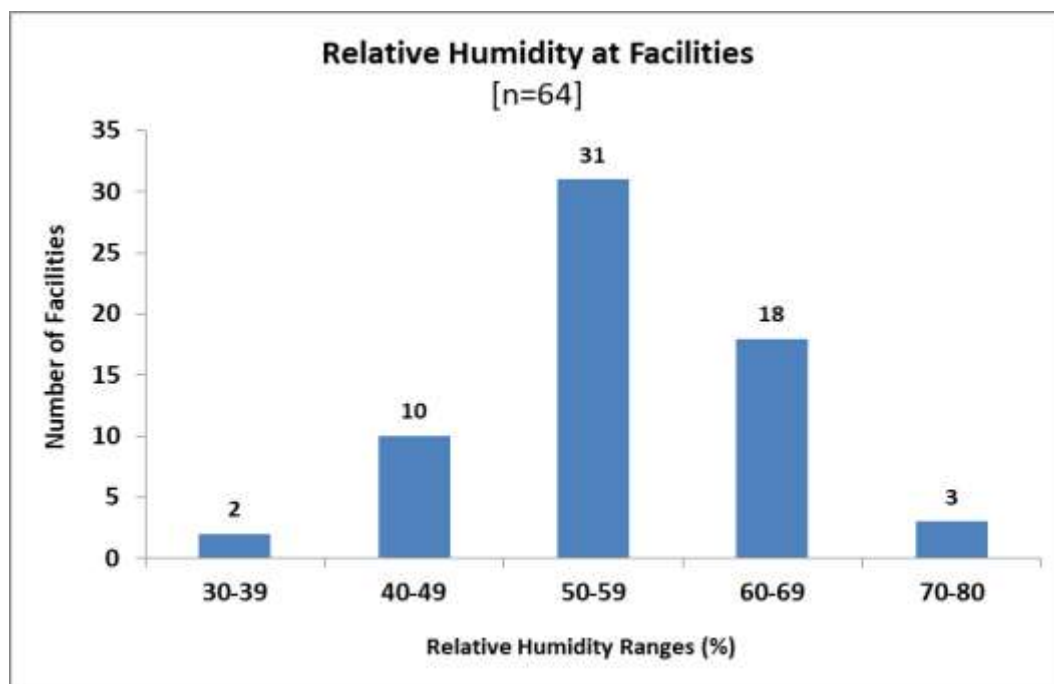


Figure 10: Frequency distribution of Relative Humidity ranges at sampled facilities

According to ICH guidelines for pharmaceutical product stability, Kenya is assigned to Climatic Zone IVb characterized as being hot and very humid zone. Consequently, the recommended long term pharmaceutical stability testing conditions for this zone specify stability of products be demonstrated upon storage for the specified shelf-life at temperatures of 30 ± 2 °C and relative humidity $75 \pm$

5%. Figure 11 below illustrates the number of products collected within and outside the upper limits of the conditions under which stability is determined.

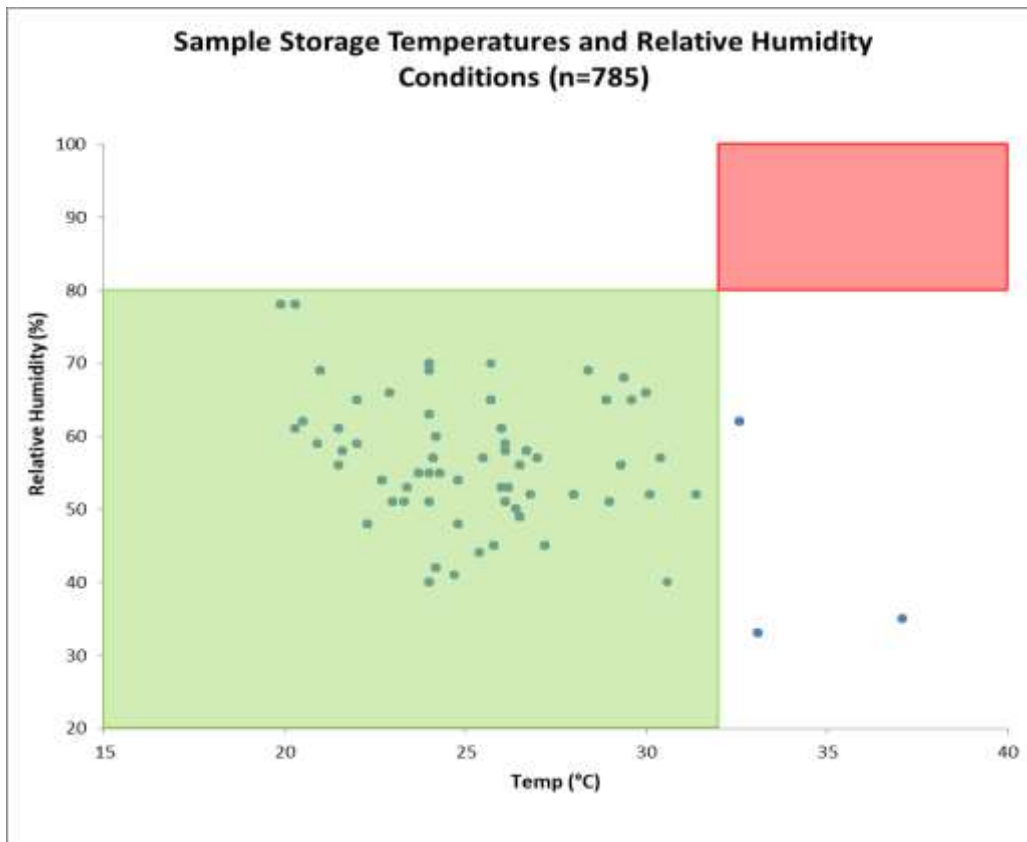


Figure 11: Combined Temperature and Relative Humidity Conditions at Sampled Facilities

A total of 26 samples were collected at facilities where temperatures exceeded 32 °C (Kinna Health Centre, Isiolo; Afya Centre, Garissa and Reenland Pharmacy; Kilifi). No facility where samples were collected was found to have relative humidity greater than 80%.

Overall, no samples were collected from any facility at which both temperature and humidity were found to exceed the upper limits recommended for stability testing conditions in Climatic Zone IVb (i.e 32 °C and 80% RH).

3.3.2 Manufacturer’s Storage Recommendations

The storage conditions at the sample collection sites were evaluated against the manufacturers’ recommended storage temperatures/conditions as specified on the individual sample product labels. Table 9 provides a summary of manufacturers’ storage specifications and the number of samples that were stored within and outside these specifications.

Table 9: Summary of manufacturers' storage specifications versus storage conditions at sampling sites

| Manufacturer's Storage Specification | Number of Samples | Stored Within Specification | Stored Outside Specification |
|---|--------------------------|------------------------------------|-------------------------------------|
| Store Below 25°C | 169 | 88 | 81 |
| Store Below 30°C | 459 | 432 | 27 |
| Store Between 10°C and 40°C | 10 | 10 | 0 |
| Store in a cool dry place | 62 | Not Determined | |
| Store at room temperature | 9 | Not Determined | |
| Do not store at extreme temperature | 1 | - | |
| Not indicated | 75 | - | |

It was observed that there was a wide variation in how different manufacturers labelled the recommended storage conditions for the samples collected. In a total of 638 (81.3%) samples, the storage temperatures were explicitly and unambiguously stated (for example "Store below 25 °C"). A total of 530 samples (83.1%) were stored within the manufacturers' recommended temperature ranges, while 108 (16.9%) were collected from facilities at which the recorded temperature was outside the manufacturers' specifications (Figure 12).

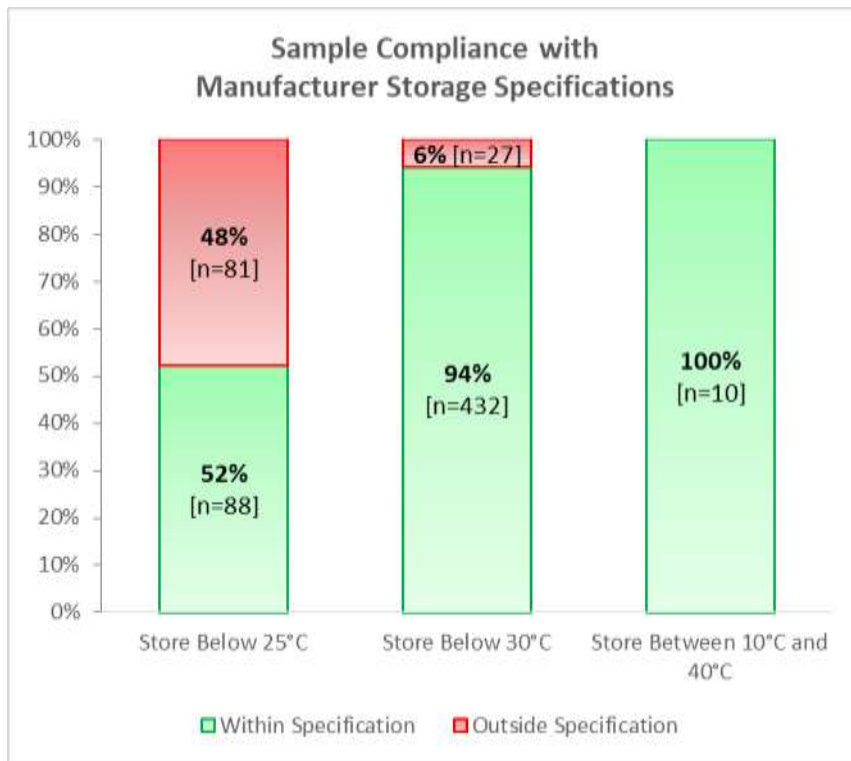


Figure 12: Sample compliance with manufacturer’s storage specifications.

There were instances in which storage conditions were non-specific and ambiguous with regard to temperature (9.2%) and more importantly, were those entirely not indicated (9.5%). In such cases, it was not possible to determine the suitability of the storage conditions recorded at the facilities from which the samples were collected.

The non-specific storage recommendations included those labeled with statements such as “Store in a cool dry place” (62 samples, including 42 medical devices), “Store at room temperature” (9 syringe samples) and “Do not store at extreme temperature” (1 syringe). The majority of samples labeled in this manner were medical devices. These samples were found to have been stored at temperatures ranging from 21 °C to 37.1 °C at the facilities from which they were collected.

3.4 Laboratory analysis results

Provided below is a summary of the 243 samples that were submitted for laboratory analysis.

Table 10: Secondary samples collected

| County | | ALB | AMX | CPR | CDM | ENP | FA | FAF | GLB | HCT | LGN | MTF | PCM | SDF | SYR | Total |
|--------------------|--------------------|-----------|-----------|-----------|-----------|-----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| Private | Machakos | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 6 |
| | Busia | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 2 | 0 | 1 | 1 | 1 | 9 |
| | Embu | 0 | 3 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 1 | 2 | 0 | 1 | 11 |
| | Garissa | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 10 |
| | Isiolo | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 6 |
| | Kajiado | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0 | 0 | 5 |
| | Meru | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0 | 1 | 5 |
| | Kilifi | 0 | 2 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 2 | 0 | 10 |
| | Kisumu | 0 | 1 | 1 | 2 | 0 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 10 |
| | Kitui | 1 | 3 | 1 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 11 |
| | Mombasa | 2 | 2 | 2 | 3 | 0 | 1 | 0 | 0 | 0 | 3 | 1 | 2 | 0 | 3 | 19 |
| | Nairobi | 2 | 5 | 2 | 4 | 1 | 0 | 1 | 2 | 1 | 4 | 2 | 4 | 3 | 3 | 34 |
| | Nakuru | 2 | 2 | 2 | 1 | 0 | 1 | 0 | 1 | 1 | 0 | 1 | 2 | 0 | 1 | 14 |
| | Narok | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 2 | 1 | 8 |
| | Trans Nzoia | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 6 |
| Uasin-Gishu | 2 | 2 | 1 | 2 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 2 | 0 | 0 | 15 | |
| Public | Isiolo | 0 | 2 | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 7 |
| | Kisumu | 1 | 2 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 0 | 1 | 2 | 0 | 3 | 14 |
| | Machakos | 0 | 2 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 8 |
| | Meru | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | Nairobi | 2 | 3 | 2 | 0 | 2 | 0 | 2 | 1 | 2 | 0 | 2 | 3 | 0 | 5 | 24 |
| | Nyeri | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 10 |
| Grand Total | | 19 | 40 | 21 | 14 | 13 | 7 | 5 | 13 | 15 | 12 | 14 | 33 | 11 | 26 | 243 |

ALB =Albendazole, AMX = Amoxicillin, CDM = Male latex condom CPR = Ciprofoxacin, ENP = Enalapril, FA = Folic acid, FAF = Folic acid & Ferrous sulphate, GLB = Glibenclamide, HCT = Hydrochlorthiazide, LNG = Levonorgestrel, MTF = Metformin, PCM = Paracetamol, SDF = Sildenafil, SYR =Syringes

3.4.1 Pharmaceutical Products

The table and figure below summarizes the compliance status of the analyzed pharmaceutical product samples (Table 11 and 13).

Table 11: Summary of compliance status of pharmaceutical products

| | Analytical Tests Performed | | | | | | | | | |
|---|----------------------------|---------------|----------------|---------------|--------------|---------------|--------------|---------------|---------------|---------------|
| | Uniformity of Weight | | Identification | | Dissolution | | Assay | | pH | |
| | Compliant | Non-Compliant | Compliant | Non-Compliant | Compliant | Non-Compliant | Compliant | Non-Compliant | Compliant | Non-Compliant |
| Albendazole Tablets | 9 | 0 | 9 | 0 | 2 | 7 | 9 | 0 | - | - |
| Albendazole Susps | - | - | 10 | 0 | - | - | 10 | 0 | 10 | 0 |
| Amoxicillin Capsules | 22 | 0 | 22 | 0 | 22 | 0 | 22 | 0 | - | - |
| Amoxicillin Susps | - | - | 13 | 0 | - | - | 12 | 1 | 13 | 0 |
| Amoxicillin Tablets | 5 | 0 | 5 | 0 | 4 | 1 | 5 | 0 | - | - |
| Ciprofloxacin Tablets | 21 | 0 | 21 | 0 | 19 | 2 | 21 | 0 | - | - |
| Enalapril Tablets | 13 | 0 | 13 | 0 | 12 | 1 | 10 | 3 | - | - |
| Folic acid Tablets | 7 | 0 | 7 | 0 | 7 | 0 | 7 | 0 | - | - |
| Folic acid/FeSO₄ Tabs | 5 | 0 | 5 | 0 | 5 | 0 | 2 | 3 | - | - |
| Glibenclamide Tablets | 13 | 0 | 13 | 0 | 13 | 0 | 13 | 0 | - | - |
| Hydrochlorothiazide | 15 | 0 | 15 | 0 | 15 | 0 | 15 | 0 | - | - |
| Levonorgestrel Tabs | 12 | 0 | 12 | 0 | 12 | 0 | 12 | 0 | - | - |
| Metformin Tablets | 14 | 0 | 14 | 0 | 14 | 0 | 14 | 0 | - | - |
| Paracetamol Tablets | 15 | 2 | 17 | 0 | 16 | 1 | 17 | 0 | - | - |
| Paracetamol Susps | - | - | 16 | 0 | - | - | 16 | 0 | 16 | 0 |
| Sildenafil Tablets | 9 | 1 | 10 | 0 | 10 | 0 | 9 | 1 | - | - |
| Sildenafil Soft-Gel | 1 | 0 | 1 | 0 | - | - | 1 | 0 | - | - |
| Total | 161 | 3 | 203 | 0 | 151 | 12 | 195 | 8 | 39 | 0 |
| % Compliance | 98.2% | 1.8% | 100.0% | 0.0% | 92.6% | 7.4% | 96.1% | 3.9% | 100.0% | 0.0% |

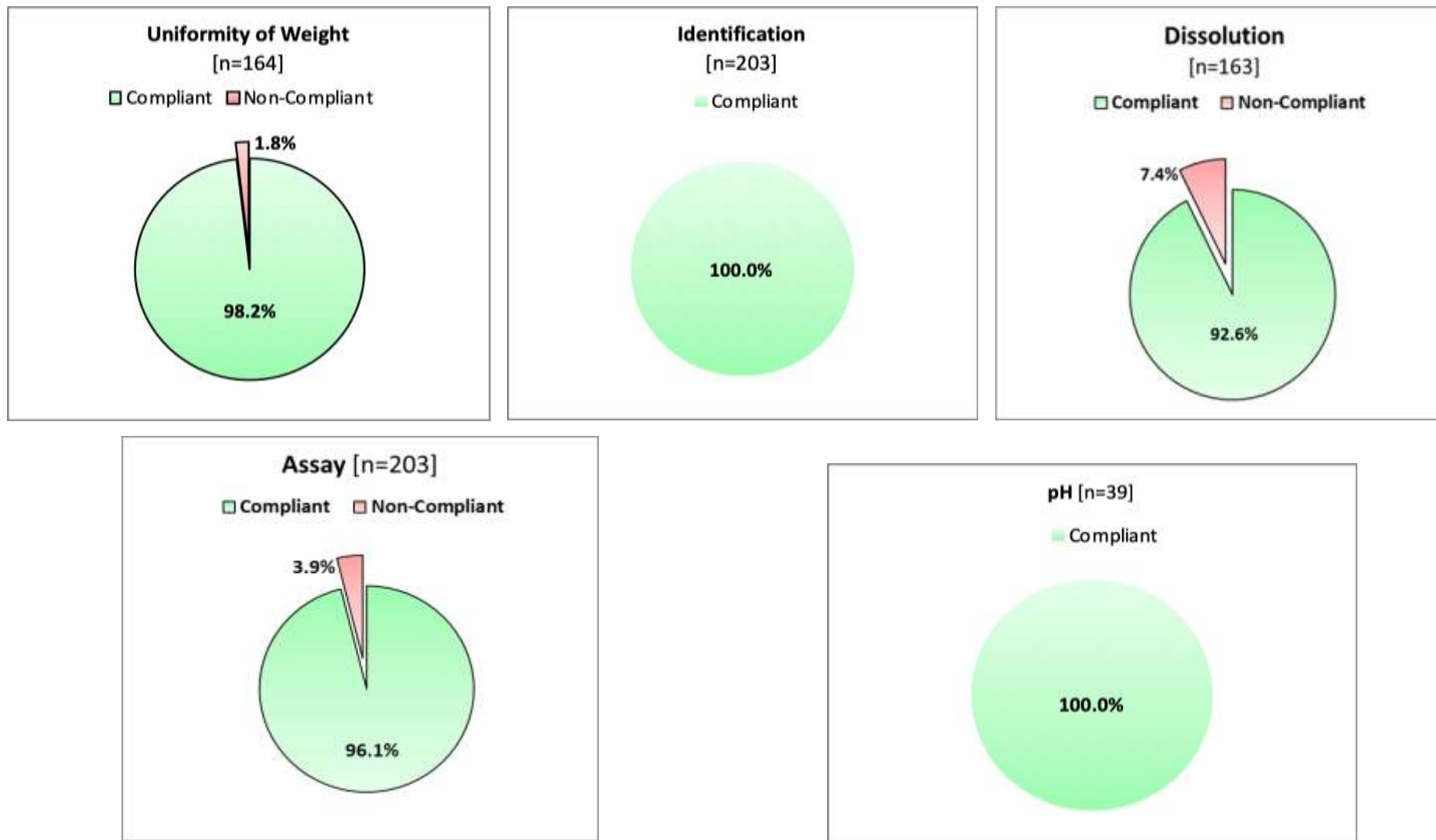


Figure 13: Graphical representation of the pharmaceutical product compliance by test performed

3.4.2 Medical Devices

Table 12 and Figure 14 below summarize the compliance status of the analyzed medical devices

Table 12: Compliance status of medical devices

| | Analytical Tests Performed | | | | | | | | | |
|-----------------------|----------------------------|---------------|-------------------------|---------------|--------------------|---------------|-------------------------|---------------|-------------|---------------|
| | Dimensions | | Burst Volume & Pressure | | Freedom from Holes | | Force to Operate Piston | | pH | |
| | Compliant | Non-Compliant | Compliant | Non-Compliant | Compliant | Non-Compliant | Compliant | Non-Compliant | Compliant | Non-Compliant |
| Condoms | 12 | 2 | 14 | 0 | 12 | 2 | - | - | - | - |
| 5 mL Syringes | - | - | - | - | - | - | 15 | 0 | 15 | 0 |
| 10 mL Syringes | - | - | - | - | - | - | 11 | 0 | 11 | 0 |
| Total | 12 | 2 | 14 | 0 | 12 | 2 | 26 | 0 | 26 | 0 |
| % Compliance | 85.7% | 14.3% | 100% | 0% | 85.7% | 14.3% | 100% | 0% | 100% | 0% |

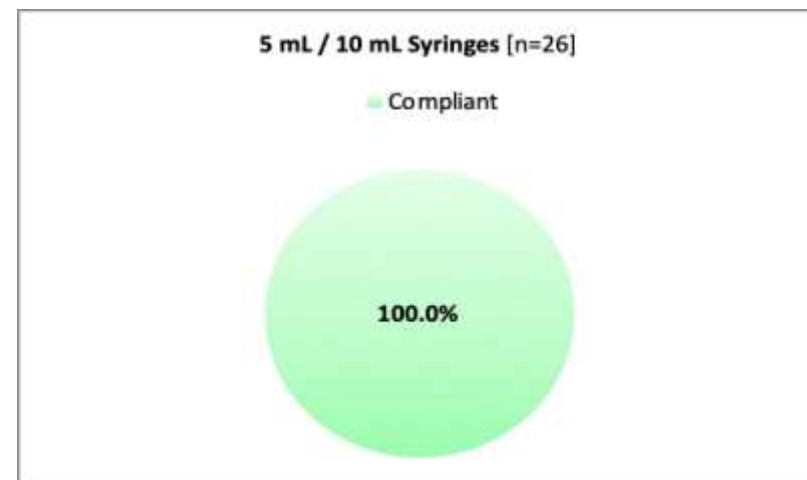
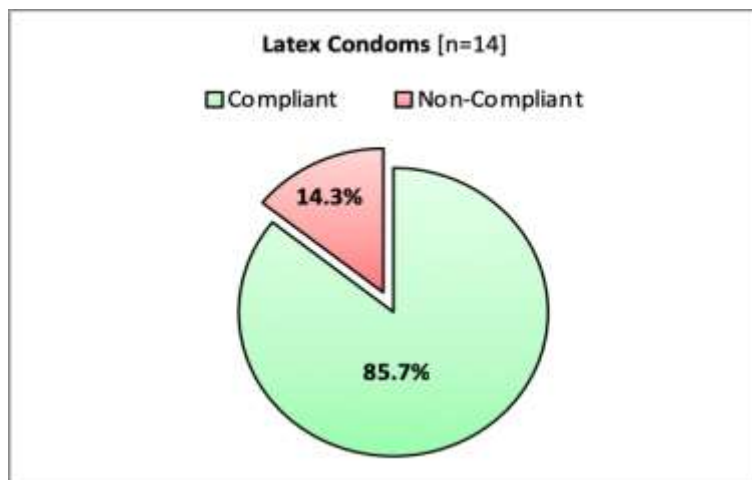


Figure 14: Graphical representation of the medical devices compliance by test performed

Figure 15 below summarizes the overall test results for the secondary samples by product type

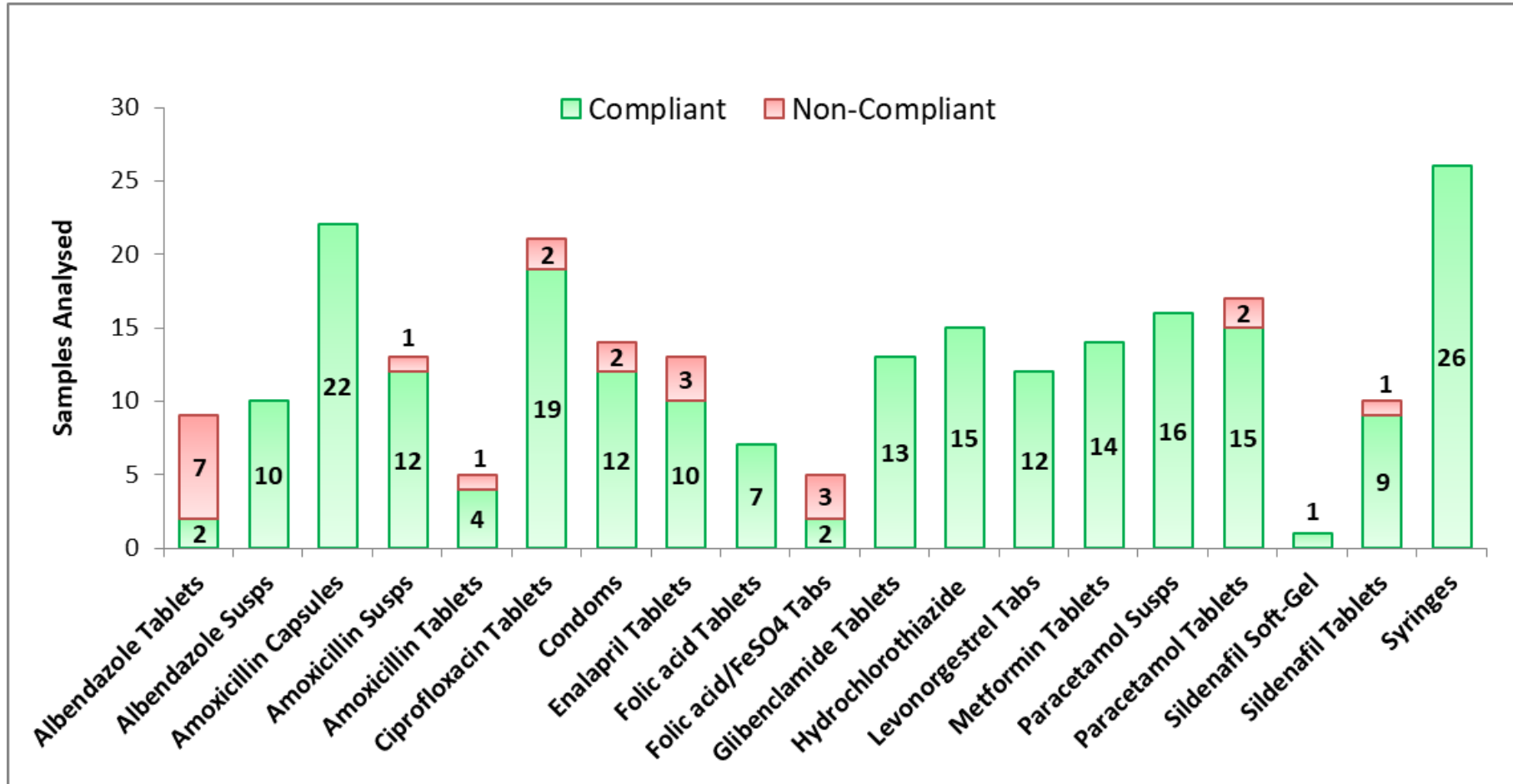


Figure 15: Graphical representation of test results [n=243]

3.4.3 Secondary sample Details and analysis results

3.4.3.1 Albendazole Tablets

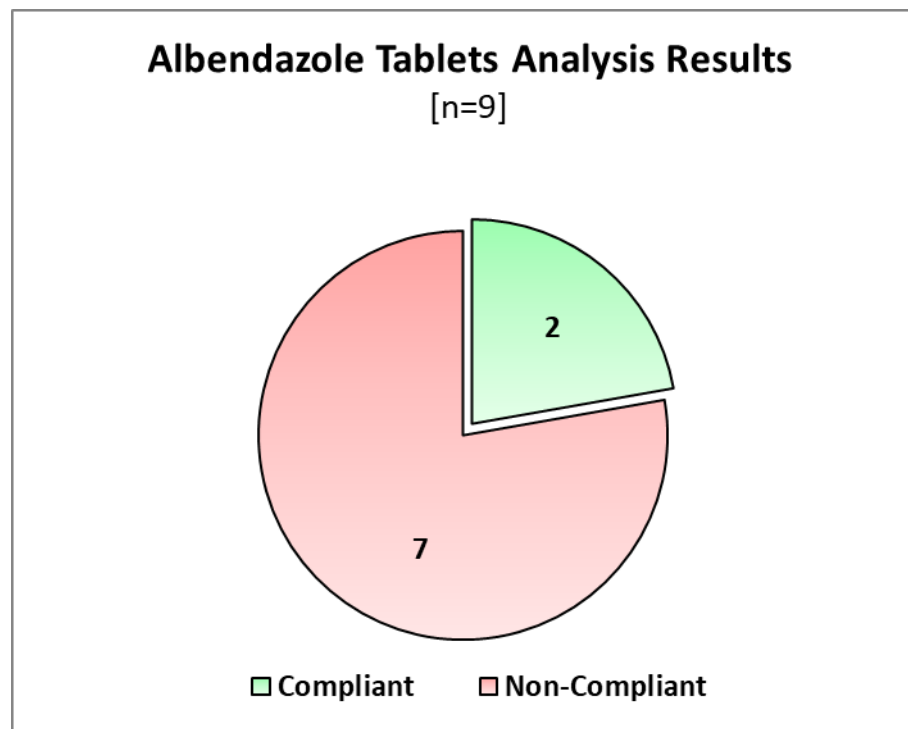


Figure 16: Compliance results for Albendazole Tablets

Table 13: Albendazole tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/2018-19/- | Assay 90.0 - 110.0% | Dissolution NLT 80% |
|----------------------------|---------|---------------------|-------------|-------------|---------------------|---------|--------------|---------------|---------------------|---------------------|
| ABLT/02/06.09.2018/ | Private | Lifecare Pharmaceut | Uasin-Gishu | ABZ Tablets | Indoco Remedies Ltd | ABX1B83 | 347 | 279 | 92.5% | 72% ¹ |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/2018-19/- | Assay 90.0 - 110.0% | Dissolution NLT 80% |
|--------------------------------|-------------|----------------------------------|----------|---------------------------------|--|---------|--------------|---------------|---------------------|---------------------|
| 028 | | icals | | | | | | | | |
| ALBT/09/04.09.2018/0046 | Private | Supreme Pharmacy | Nakuru | Alben Tablets | Medreich Limited | 370987 | 348 | 280 | 96.5% | 92% |
| ALBT/04/03.09.2018/002 | Private | Shifa Chemist | Mombasa | Zentel™ 400 mg Chewable Tablets | Glaxosmithkline South Africa (Pty) Ltd | 373751 | 349 | 281 | 96.8% | 87% |
| ALBT/08/07.09.2018/049 | Private | Nunguni Chemists Ltd | Kitui | Almex® 400 Tablets | Square Pharmaceuticals Ltd | 8A02937 | 350 | 282 | 95.1% | 20% ¹ |
| ALBT/01/04.09.2018/030 | Public | Kenya Medical Supplies Authority | Nairobi | Wombit Tablets | Biodeal Laboratories Ltd | 0218071 | 351 | 283 | 92.2% | 15% ¹ |
| ALBT/01/04.09.2018/032 | Public | Kenya Medical Supplies Authority | Nairobi | Wombit Tablets | Biodeal Laboratories Ltd | 0218072 | 352 | 284 | 92.6% | 16% ¹ |
| ALBT/06/08.09.2018/053 | Public | Meru District Hospital | Meru | Wombit Tablets | Biodeal Laboratories Ltd | 0317120 | 353 | 285 | 93.3% | 4% ¹ |
| ALBT/07/06.09.2018/017 | Public | Karatina District Hospital | Nyeri | Wombit Tablets | Biodeal Laboratories Ltd | 0717070 | 354 | 286 | 94.8% | 7% ¹ |
| ALBT/05/07.09.2018/046 | Faith-Based | Bishop Kioko Catholic Hospital | Machakos | ABZ Tablets | Indoco Remedies Ltd | ABX1B83 | 356 | 287 | 95.0% | 77% ¹ |

¹Failed Dissolution test NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All nine samples of albendazole tablets were analyzed and complied with the specifications for uniformity of weight, identity and content of the active ingredient (assay). However, seven (7) samples failed to comply with the specification for dissolution test for albendazole chewable tablets.

3.4.3.2 Albendazole oral suspensions

Table 14: Albendazole oral suspensions sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | pH 4.5 – 5.5 |
|---------------------------------|-------------|---|-----------------|-------------------------------|-----------------------------------|----------|--------------|----------------|---------------------|--------------|
| ALBS/01/0 6.09.2018/ 062 | Private | Surgipharm Ltd | Nairobi | Alben™ Oral Suspension | Panacea Biotec Ltd | 54517008 | 355 | 227 | 91.6% | 5.4 |
| ALBS/03/0 5.09.2018/ 071 | Private | Scorpion Pharmacy | Busia | Emitel® Suspension | Njimia (K) Limited | 06408 | 360 | 228 | 93.4% | 5.3 |
| ALBS/01/0 5.09.2018/ 060 | Private | Harleys Pharmaceut icals | Nairobi | Tanzol™ Oral Suspension | Gopaldas Visram And Co. Ltd | G8009 | 362 | 229 | 99.6% | 5.2 |
| ALBS/09/0 3.09.2018/ 0015 | Private | Transwide Pharmaceut icals | Nakuru | Olworm® Oral Suspension | Biopharma Ltd | BPL450 | 363 | 230 | 98.3% | 4.9 |
| ALBS/02/0 5.09.2018/ 014 | Private | Pilot Pharmaceut icals | Uasin- Gishu | Tanzol™ Oral Suspension | Gopaldas Visram And Co. Ltd | G8006 | 364 | 231 | 101.4% | 5.2 |
| ALBS/03/0 4.09.2018/ 032 | Public | Ahero County Hospital | Kisumu | Benaworm Suspension | Benmed Pharmaceutica l Ltd | 01018 | 365 | 232 | 93.8% | 5.2 |
| ALBS/04/0 5.09.2018/ 019 | Private | Makadara Chemist | Mombasa | Albasol Suspension | Regal Pharmaceutica ls Ltd | 171908 | 357 | 234 | 100.0% | 4.7 |
| ALBS/08/0 5.09.2018/ 014 | Private | Ummah Pharmacy | Garissa | Zentel™ Suspension | Farmaclair | 8024 | 358 | 235 | 92.4% | 5.3 |
| ALBS/06/0 7.09.2018/ 0031 | Faith-Based | Matercare Maternity Hospital | Isiolo | Emitel® Suspension | Njimia (K) Limited | 94407 | 359 | 236 | 92.6% | 5.3 |
| ALBS/05/0 7.09.2018/ 045 | Faith-Based | Bishop Kioko Catholic Hospital | Machakos | ABZ Oral Suspension | Indoco Remedies Ltd | AAC2A83 | 361 | 237 | 105.8% | 5.2 |

²Failed assay test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All the ten (10) samples tested complied with the requirements for the tests performed.

3.4.3.3 Amoxicillin capsules

Table 15: Amoxicillin capsules sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809 | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|-------------------------------|---------|------------------------------------|-------------|-------------------------|---|-----------|-------------|----------------|---------------------|---------------------|
| AMX5/08/08.09.2018/065 | Private | Stera Pharmacy | Kitui | Omacillin 500 Capsules | National Pharmaceuticals Industries Co. (SAOG) | 317317 | 104 | 150 | 98.0% | 90% |
| AMX5/02/05.09.2018/012 | Private | Pilot Pharmaceuti cals | Uasin-Gishu | Amoximed 500mg Capsules | CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd | 706171211 | 105 | 163 | 97.2% | 92% |
| AMX5/03/03.09.2018/003 | Public | Nyanza Provincial General Hospital | Kisumu | Spamox - 500 Capsules | Sparsh Bio-Tech Pvt. Ltd | MX230 | 106 | 159 | 96.7% | 94% |
| AMX5/07/10.09.2018/075 | Private | T. D Concept | Embu | Moxacil - 500 Capsules | Dawa Limited | 1802089 | 107 | 218 | 98.9% | 93% |
| AMX5/03/06.09.2018/096 | Private | Laborex | Kisumu | Amoxil 500 mg Capsules | Glaxo Wellcome Production | MJ2M | 108 | 156 | 95.5% | 89% |
| AMX5/01/04.09.2018/028 | Public | Kenya Medical Supplies Authority | Nairobi | Omacillin 500 Capsules | National Pharmaceutical Industries Co. (SAOG) | 0318305 | 109 | 151 | 99.1% | 98% |
| AMX5/01/04.09.2018/029 | Public | Kenya Medical Supplies Authority | Nairobi | Omacillin 500 Capsules | National Pharmaceutical Industries Co. (SAOG) | 0318304 | 110 | 164 | 99.9% | 92% |
| AMX5/01/03.09.2018/021 | Public | Kenya Medical Supplies Authority | Nairobi | Omacillin 500 Capsules | National Pharmaceutical Industries Co. (SAOG) | 318303 | 111 | 160 | 99.1% | 93% |
| AMX5/06/ | Faith- | Matercare | Isiolo | Amoximed | CSPC Zhongnuo | 706180196 | 112 | 155 | 99.2% | 99% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809 | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------|---------|----------------------------|----------|-----------------------------|---|-----------|-------------|----------------|---------------------|---------------------|
| 07.09.2018 /0033 | Based | Maternity Hospital | | 500 mg Capsules | Pharmaceutical (Shijiazhuang) Co. Ltd | | | | | |
| AMX5/09/04.09.2018 /0037 | Private | Supreme Pharmacy | Nakuru | Moxilact 500 mg Capsules | Reyoung Pharmaceuticals Co., Ltd | 173132010 | 113 | 213 | 98.3% | 102% |
| AMX5/04/05.09.2018 /027 | Private | Makadara Chemist | Mombasa | Asmox - 500 Capsules | Astra Lifecare (India) Pvt. Ltd | 299 | 114 | 214 | 95.9% | 95% |
| AMX5/05/04.09.2018 /014 | Public | Kangundo District Hospital | Machakos | Moximed Capsules | Medivet Products Ltd | P2942 | 115 | 149 | 96.1% | 88% |
| AMX2/04/08.09.2018 /064 | Private | Sabaki Pharmacy | Kilifi | Omacillin 250 mg Capsules | National Pharmaceutical Industries Co. (SAOG) | 0318004 | 116 | 165 | 100.4% | 100% |
| AMX2/05/11.09.2018 /061 | Private | Lenana Pharmaceuticals Ltd | Kajiado | Caremox - 250 Capsules | Shanxi Xinyitong Pharmaceutical Co., Ltd | 170519 | 117 | 154 | 95.2% | 98% |
| AMX2/01/10.09.2018 /110 | Private | Transchem | Nairobi | Elymox 250 mg Capsules | Elys Chemical Industries Ltd | 8C14 | 118 | 147 | 97.3% | 90% |
| AMX2/09/03.09.2018 /0006 | Private | Transwide Pharmaceuticals | Nakuru | Amoxil 250 mg Capsules | Glaxo Wellcome Production | MJ2N | 119 | 217 | 94.0% | 97% |
| AMX2/08/07.09.2018 /054 | Private | Nunguni Chemists Ltd | Kitui | Kemoxyl 250 mg Capsules | Laboratory & Allied Ltd | 72240 | 120 | 161 | 99.8% | 97% |
| AMX2/01/09.09.2018 /082 | Private | Rafiki Pharmaceuticals | Nairobi | Amoxil 250 mg Capsules | Glaxo Wellcome Production | MJ2N | 121 | 166 | 95.9% | 95% |
| AMX2/06/04.09.2018 /0001 | Public | Kinna Health Centre | Isiolo | Amoxicillin 250 mg Capsules | Zhejiang Holley Nanhu Pharmaceutical Co., Ltd | 160658 | 122 | 162 | 96.7% | 102% |
| AMX2/05/ | Faith- | Bishop Kioko | Machakos | Amoximed | CSPC Zhongnuo | 767180133 | 123 | 215 | 94.9% | 98% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809 - | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------------|---------|-------------------|-------------|------------------------|------------------------------|---------|---------------|----------------|---------------------|---------------------|
| 07.09.2018 /038 | Based | Catholic Hospital | | 250 mg Capsules | Pharmaceuticals Co. Ltd | | | | | |
| AMX2/07/10.09.2018 /051 | Private | Itabua Chemist | Embu | Elymox 250 mg Capsules | Elys Chemical Industries Ltd | 6D24 | 124 | 148 | 97.0% | 97% |
| AMX2/02/07.09.2018 /030 | Private | Sarara Chemist | Trans Nzoia | Moxacil - 250 Capsules | Dawa Limited | 1806191 | 125 | 216 | 95.7% | 90% |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All the 22 amoxicillin capsule samples complied with the requirements for the tests performed.

3.4.3.4 Amoxicillin Dispersible Tablets

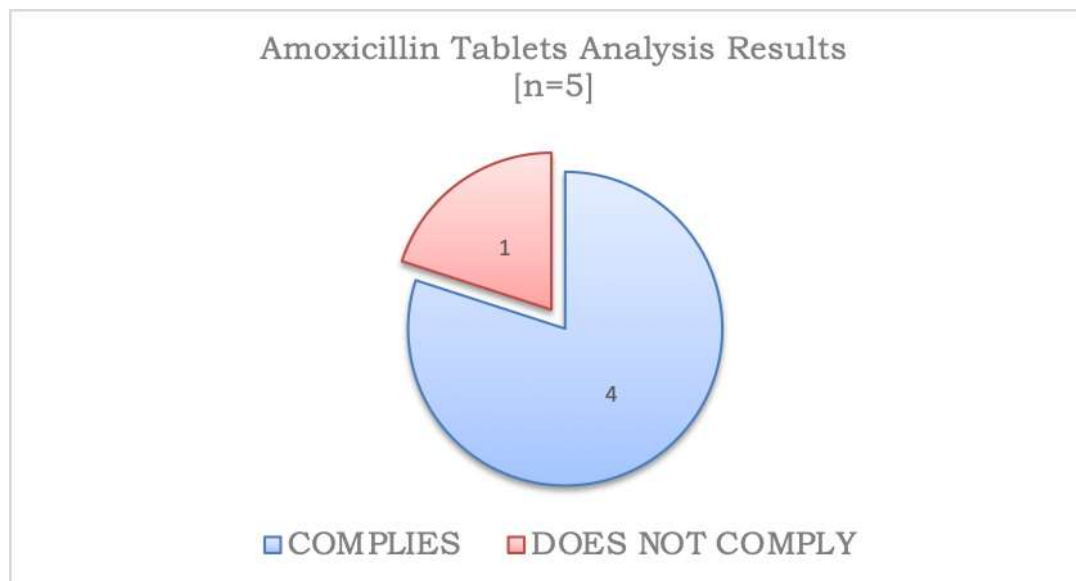


Figure 17: Compliance results for Amoxicillin dispersible tablets

Table 16: Amoxicillin dispersible tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 80% |
|--------------------------------|---------|--------------------------|---------|---|--------------------|-----------|--------------|----------------|---------------------|---------------------|
| AMXT/06/06.09.2018/0014 | Public | Isiolo District Hospital | Isiolo | Amoxicillin Dispersible Tablets 250 mg* | Micro Labs Limited | ACTHV0254 | 129 | 373 | 97.2 | 102 |
| AMXT/01/10.09.2018/095 | Private | Nila Pharmaceuticals | Nairobi | Amoxicillin 250 mg Dispersible Tablets | Sandoz GmbH | HH2065 | 128 | 372 | 95.9 | 87 |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 80% |
|--------------------------------|---------|--------------------------------|--------|--|-------------------------|--------------|--------------|----------------|---------------------|---------------------|
| AMXT/09/06.09.2018/0053 | Private | Jaslim Pharmacy | Narok | Amoxicillin 250 mg Dispersible Tablets | Sandoz GmBH | HB1918 | 127 | 371 | 94.8 | 85 |
| AMXT/07/06.09.2018/015 | Public | Karatina District Hospital | Nyeri | Medomox 250 DT Tablets | Medopharm Pvt. Ltd | (10)17442007 | 126 | 370 | 94.4 | 83 |
| AMXT/03/04.09.2018/026 | Public | Muhoroni Sub-District Hospital | Kisumu | Kemoxyl® DT 250 Tablets | Laboratory & Allied Ltd | 69660 | 130 | 374 | 91.2 | 77 ¹ |

¹Failed Dissolution test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All the five (5) amoxicillin dispersible samples complied with the requirements for uniformity of weight, identification and assay. However, one (1) sample failed dissolution test.

3.4.3.5 Amoxicillin oral suspension

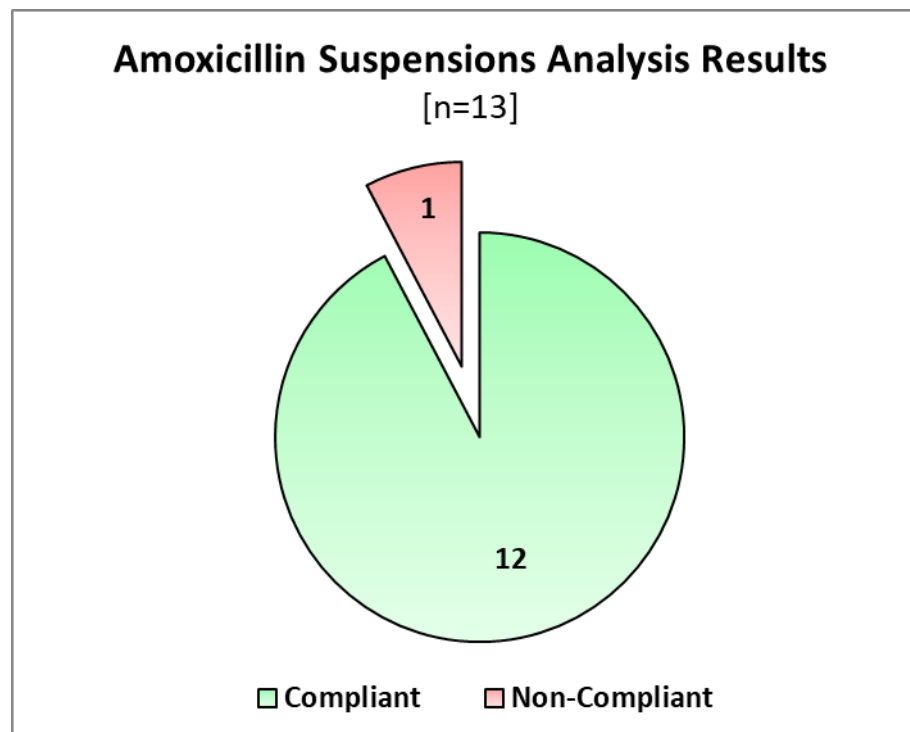


Figure 18: Compliance results for Amoxicillin oral suspension

Table 17: Amoxicillin oral suspension sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018- 19/- | Assay 90.0 – 120.0% | | pH 5.0 – 7.5 |
|--------------------------------|---------|------------------|--------|------------------------|-------------------------|-----------|--------------|-----------------|---------------------|--------|--------------|
| | | | | | | | | | Day 1 | Day 7 | |
| AMX5/07/10. 09.2018/055 | Private | Itabua Chemist | Embu | Labmox Oral Suspension | Laborate Pharmaceutical | ILBDE-004 | 133 | 381 | 116.6% | 115.6% | 6.1 |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018- 19/- | Assay 90.0 – 120.0% | | pH 5.0 – 7.5 |
|--|-----------------|--------------------------------|---------|--|------------------------------|---------|-----------------|-----------------------|------------------------|--------|--------------------|
| | | | | | | | | | Day 1 | Day 7 | |
| | | | | 125 mg/ 5 mL BP | s India Ltd | | | | | | |
| AMXS/04/10. 09.2018/068 | Private | Azmon Pharmac y | Kilifi | Spamox 125 Dry Powder For Suspension | Sparsh Bio- Tech Pvt. Ltd | X0798 | 139 | 194 | 103.6% | 98.9% | 6.1 |
| AMXS/08/07. 09.2018/041 | Private | Nunguni Chemists Ltd | Kitui | Moxacil 125 mg/5 mL Amoxicillin BP Suspension | Dawa Limited | 1711299 | 141 | 375 | 95.5% | 94.6% | 6.1 |
| AMXS/01/06. 09.2018/067 | Private | Surgiphar m Ltd | Nairobi | Penamox 125 mg/5 mL Powder For Oral Suspension | Medreich Limited | 810042 | 143 | 196 | 109.1% | 102.9% | 6.6 |
| AMXS/03/05. 09.2018/068 | Private | Scorpion Pharmac y | Busia | Kemoxyl Dry Suspension | Laboratory & Allied Ltd | 71667 | 140 | 195 | 100.3% | 97.0% | 6.2 |
| AMXS/09/06. 09.2018/004 8 | Private | Jaslim Pharmac y | Narok | Spamox 125 Dry Powder For Suspension | Sparsh Bio- Tech Pvt. Ltd | X0799 | 138 | 193 | 108.8% | 107.6% | 6.4 |
| AMXS/01/10 /09.2018/13 2 | Private | Generics Africa | Nairobi | Amoxil Forte 250 mg Powder for Oral Suspension | Glaxo Wellcome Production | 536P | 137 | 192 | 101.1% | 97.8% | 6.3 |
| AMXS/08/06. 09.2018/017 | Private | Medina Pharmac y Limited | Garissa | Amoxil 125 mg/5 ml Powder For Suspension | Glaxo Wellcome Production | 490 | 135 | 191 | 96.0% | 99.7% | 6.2 |
| AMXS/06/10. 09.2018/071 | Faith- Based | St Theresa Kiirua | Meru | Moximed Dry Powder For Suspension | Medivet Products Ltd | S7001 | 134 | 190 | 111.1% | 98.8% | 6.5 |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018- 19/- | Assay 90.0 – 120.0% | | pH 5.0 – 7.5 |
|------------------------------------|---------|-----------------------------------|-----------------|--|--|---------------|-----------------|-----------------------|------------------------|---------------------|--------------------|
| | | | | | | | | | Day 1 | Day 7 | |
| | | Hospital | | | | | | | | | |
| AMXS/04/05. 09.2018/021 | Private | Makadar a Chemist | Mombas a | Kemoxyl Dry Suspension | Laboratory & Allied Ltd | 72249 | 132 | 189 | 103.9% | 102.5% | 6.6 |
| AMXS/05/03. 09.2018/005 | Public | Athi River Health Centre | Machak os | Kemoxyl Dry Suspension | Laboratory & Allied Ltd | 70214 | 131 | 188 | 105.5% | 107.8% | 6.4 |
| AMXS/02/07. 09.2018/038 | Private | Sarara Chemist | Trans Nzoia | Elymox 125 mg/ 5 mL Oral Suspension BP | Elys Chemical Industries Ltd | 8E62 | 136 | 380 | 98.5% | 96.3% | 5.5 |
| AMXS/02/05. 09.2018/013 | Private | Pilot Pharmac euticals | Uasin- Gishu | Labmox Oral Suspension 125 mg/ 5 mL BP | Laborate Pharmaceuti s India Ltd | ILBDE- 003 | 142 | 376 | 132.8% ² | 130.5% ² | 5.9 |

²Failed Assay test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

Twelve (12) out of the thirteen amoxicillin oral suspensions complied with the requirements for the tests performed. One (1) sample failed to comply with the specification for the assay test and was found to consistently contain higher levels of amoxicillin than specified (120%), when freshly reconstituted (132.8%) and even seven (7) days after reconstitution (130.5%).

3.4.3.6 Ciprofloxacin tablets

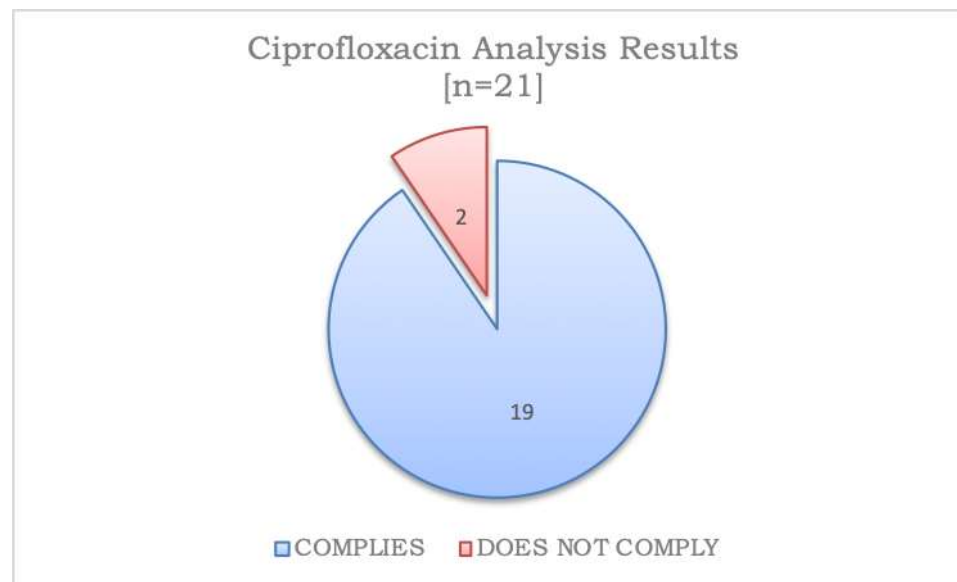


Figure 19: Compliance results for Ciprofloxacin tablets

Table 18: Ciprofloxacin tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|-------------------------------|-------------|------------------------------|-------------|-------------------------|---------------------------|---------|--------------|----------------|---------------------|---------------------|
| CPR5/06/07.09.2018/034 | Faith-Based | Matercare Maternity Hospital | Isiolo | Strox Tablets | Universal Corporation Ltd | 5802163 | 192 | 314 | 96.6% | 47% ¹ |
| CPR5/08/07.09.2018/044 | Private | Nunguni Chemists Ltd | Kitui | Ciprokant - 500 Tablets | S. Kant Healthcare Ltd | CX6049 | 181 | 181 | 97.2% | 100% |
| CPR5/02/06.09.2018/ | Private | Eldohosp Pharmaceuti | Uasin-Gishu | Ciprozed - 500 | Zest Pharma | TE6218 | 184 | 182 | 92.7% | 102% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------------|-------------|----------------------------------|----------|----------------------------------|-----------------------------------|------------|--------------|----------------|---------------------|---------------------|
| 029 | | cals | | Tablets | | | | | | |
| CPR5/05/07.09.2018/040 | Faith-Based | Bishop Kioko Catholic Hospital | Machakos | Ciflo Tablets | Elys Chemical Industries Ltd | 8E97 | 185 | 183 | 95.7% | 103% |
| CPR5/08/06.09.2018/019 | Private | Medina Pharmacy Limited | Garissa | Ciprobay 500 Tablets | Bayer Pharma AG | BXHHZG1 | 186 | 184 | 97.6% | 101% |
| CPR5/04/07.09.2018/055 | Private | Reenland Pharmacy | Kilifi | Ciprointa - 500 Tablets | Intas Pharmaceutic als Ltd | DW1434 | 189 | 185 | 98.7% | 110% |
| CPR5/01/04.09.2018/042 | Public | Kenya Medical Supplies Authority | Nairobi | Ciprofloxacin Tablets USP 250 mg | Kopran Limited | LQK4528004 | 198 | 186 | 94.4% | 93% |
| CPR2/01/04.09.2018/038 | Public | Kenya Medical Supplies Authority | Nairobi | Ciprocos - 250 Tablets | Cosmos Limited | 81113 | 199 | 187 | 96.8% | 96% |
| CPR2/06/04.09.2018/0007 | Public | Kinna Health Centre | Isiolo | Ciprocos - 250 Tablets | Cosmos Limited | 70683 | 195 | 206 | 97.0% | 100% |
| CPR2/04/12.09.2018/071 | Private | Surgipharm Ltd Mombasa | Mombasa | Ciprobay 250 Tablets | Bayer Pharma AG | ITA33A5 | 194 | 207 | 96.7% | 107% |
| CPR5/04/12.09.2018/086 | Private | Eldohosp Pharmaceuti cals | Mombasa | Kuin 500 mg Tablets | P.D.H Pharmaceutic als (Pvt.) Ltd | 707755 | 187 | 208 | 99.8% | 102% |
| CPR5/09/04.09.2018/0041 | Private | Supreme Pharmacy | Nakuru | Ultraflox - 500 Tablets | Bal Pharma Ltd | UTF 286 | 182 | 209 | 101.4% | 102% |
| CPR5/07/10.09.2081/049 | Private | Itabua Chemist | Embu | Ciprofred - 500 Tablets | Fredun Pharmaceutic als Ltd | FT079 | 177 | 210 | 96.8% | 105% |
| CPR5/01/10.09.2018/ | Private | Transchem | Nairobi | Omacip* 500 | National Pharmaceutic | 2017329 | 180 | 219 | 97.2% | 101% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------------|---------|-----------------------------------|-------------|-------------------------|---|---------|--------------|----------------|---------------------|---------------------|
| 0116 | | | | Tablets | al Industries Co. (SAOG) | | | | | |
| CPR5/03/06.09.2018/077 | Private | Victoria Healthcare | Kisumu | Omacip* 500 Tablets | National Pharmaceutical Industries Co. (SAOG) | 2017328 | 183 | 220 | 96.3% | 98% |
| CPR5/02/07.09.2018/039 | Private | Sarara Chemist | Trans Nzoia | Ceeepro 500 Tablets | Lincoln Pharmaceuticals Ltd | DY8003 | 188 | 221 | 97.4% | 103% |
| CPR5/05/07.09.2018/053 | Private | Lenana Pharmaceuticals Ltd | Kajiado | Cipointa - 500 Tablets | Intas Pharmaceuticals Ltd | DW1435 | 190 | 222 | 97.0% | 103% |
| CPR5/09/03.09.2018/0012 | Private | Trans wide Pharmaceuticals | Nakuru | Cipcina - 500 Tablets | Shandong Shenglu Pharmaceutical Co., Ltd | 170520 | 191 | 223 | 93.1% | 62% ¹ |
| CPR5/01/09.09.2018/086 | Private | Rafiki Pharmaceuticals | Nairobi | Ciflosin 500 mg Tablets | Deva Holding A. S. | A055411 | 193 | 224 | 98.4% | 100% |
| CPR2/03/06.09.2018/075 | Public | Kisumu County Hospital | Kisumu | Ciprocos - 250 Tablets | Cosmos Limited | 80183 | 196 | 225 | 96.3% | 102% |
| CPR5/07/07.09.2018/036 | Public | Nyeri Provincial General Hospital | Nyeri | Ciprocos - 250 Tablets | Cosmos Limited | 61042A | 197 | 226 | 97.1% | 101% |

¹Failed Dissolution Test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

Nineteen (19) out of the twenty-one (21) samples tested complied with the requirements for all the tests performed.

However, two (2) products did not meet the dissolution requirements

3.4.3.7 Enalapril Tablets

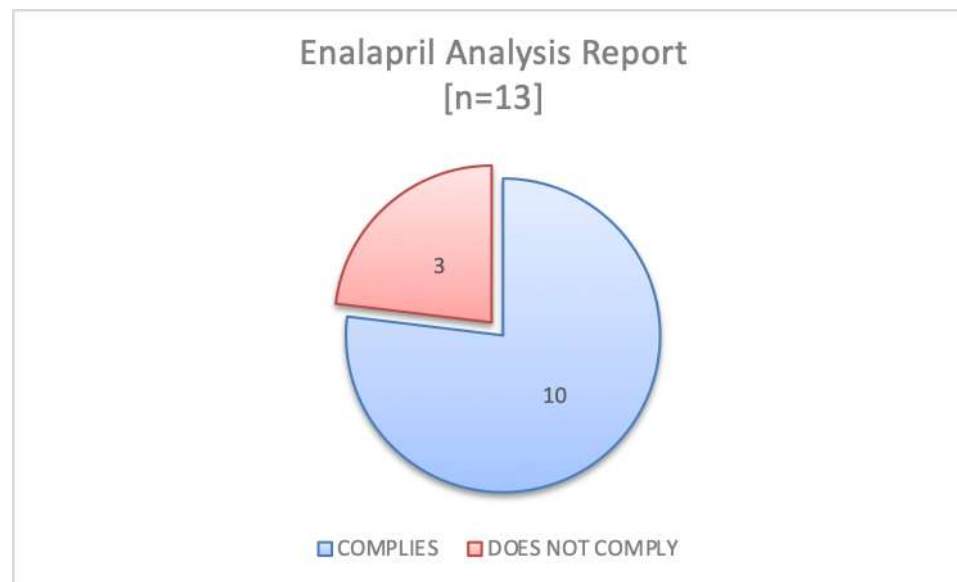


Figure 20: Compliance results for Enalapril tablets

Table 19: Enalapril tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 20180 9- | CAN/ 2018- 19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|---------------------------------|--------|------------------------------------|---------|--------------------|--------------------------------------|---------|---------------|-----------------|---------------------|---------------------|
| ENP5/01/0 3.09.2018/ 006 | Public | Kenya Medical Supplies Authority | Nairobi | Acepril-5® Tablets | Laboratory & Allied Ltd | 72061 | 206 | 352 | 85.1% ² | 85% ³ |
| ENP5/07/0 7.09.2018/ 033 | Public | Nyeri Provincial General Hospital | Nyeri | Acepril-5® Tablets | Laboratory & Allied Ltd | 70439 | 205 | 351 | 78.0% ² | 79% ³ |
| ENP5/03/0 3.09.2018/ | Public | Nyanza Provincial General Hospital | Kisumu | Enacare Tablets | Shandong Shenglu Pharmaceutical Co., | 180150 | 201 | 350 | 18.5% ² | 18% ¹ |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 20180 9- | CAN/ 2018- 19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|----------------------------------|-------------|------------------------------|-------------|------------------------|-----------------------------|----------|---------------|-----------------|---------------------|---------------------|
| 005 | | | | | Ltd | | | | | |
| ENP5/09/0 6.09.2018/ 0062 | Private | Nenkai Pharmaceutical Stores | Narok | Enaril® Tablets | Beximco Pharmaceuticals Ltd | SAK180 | 200 | 238 | 101.0% | 108% |
| ENP5/02/0 5.09.2018/ 006 | Private | Pilot Pharmaceuticals | Uasin-Gishu | Encardil 5 Tablets | Medley Pharmaceuticals Ltd | D70941 | 202 | 239 | 99.7% | 108% |
| ENP5/04/0 7.09.2018/ 047 | Private | Old Madaraka Chemist | Kilifi | Enapril - 5 Tablets | Intas Pharmaceuticals Ltd | DX006 1 | 203 | 240 | 99.5% | 104% |
| ENP5/06/0 7.09.2018/ 035 | Faith-Based | Matercare Maternity Hospital | Isiolo | Vasopril® 5 Tablets | Square Pharmaceuticals Ltd | 6F0217 8 | 204 | 241 | 90.9% | 102% |
| ENP5/01/0 7.09.2018/ 072 | Public | Kenyatta National Hospital | Nairobi | Cardace® 5 mg Tablets | Cosmos Limited | 71212 | 207 | 242 | 99.9% | 107% |
| ENP1/05/0 6.09.2018/ 031 | Public | Machakos Level 5 Hospital | Machakos | Cardace® 10 mg Tablets | Cosmos Limited | 70664 | 208 | 243 | 100.5% | 91% |
| ENP1/01/1 0.09.2018/ 094 | Private | Nila Pharmaceuticals | Nairobi | Enril 10 Tablets | Prism Life Sciences Limited | KN1130 | 209 | 244 | 98.2% | 84% |
| ENP1/08/0 6.09.2018/ 025 | Private | Medina Pharmacy Limited | Garissa | Dawapril 10 Tablets | Dawa Limited | 170714 0 | 210 | 245 | 96.6% | 86% |
| ENP1/07/1 0.09.2018/ 064 | Private | Mbeti Pharmacy | Embu | Encardil 10 Tablets | Medley Pharmaceuticals Ltd | D70848 | 211 | 246 | 96.0% | 87% |
| ENP1/03/0 5.09.2018/ 063 | Private | Scorpion Pharmacy | Busia | Encardil 10 Tablets | Medley Pharmaceuticals Ltd | D70849 | 212 | 247 | 102.8% | 94% |

¹Failed Dissolution test, ²Failed Assay test, ³BP monograph used with dissolution limits of NLT 70%, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

Ten (10) out of the thirteen (13) samples tested complied with the requirements for all the tests performed. Three (3) samples did not meet requirements for one or more of the tests. While all of the three failed on assay test, two complied with dissolution and uniformity of weight tests, whereas one product (Enacare 5 mg) failed significantly on both assay (18.5%) and dissolution (18%).

3.4.3.8 Folic Acid/Folic acid and Ferrous Sulphate Fixed Dose Combinations (FDC)

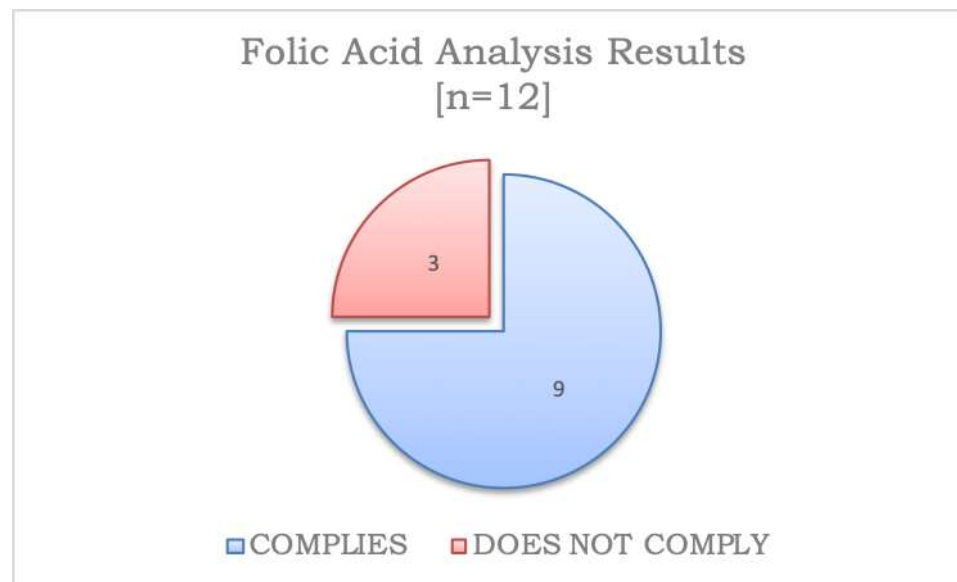


Figure 21: Compliance results for Folic Acid tablets

Table 20: Folic Acid/Folic acid and Ferrous Sulphate Fixed Dose Combinations (FDC) tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 20180 9- | CAN/ 2018- 19/- | Assay 90.0 – 115.0% | Dissolution NLT 80% |
|---------------------------------|---------|----------------------------------|----------|-------------------------|-----------------------------|---------|---------------|-----------------|---------------------|---------------------|
| FEFT/01/0 4.09.2018/ 034 | Public | Kenya Medical Supplies Authority | Nairobi | Ferrollic - LF® Tablets | Laboratory & Allied Limited | 71629 | 262 | 342 | 104.4% | 103% |
| FEFT/05/0 4.09.2018/ 019 | Public | Kangundo District Hospital | Machakos | Ferrollic - LF® Tablets | Laboratory & Allied Limited | 70268 | 261 | 341 | 98.8% | 96% |
| FAFT/09/0 | Private | Elim Central | Nakuru | Folvite | Not Indicated | T129 | 257 | 349 | 102.6% | 98% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 20180 9- | CAN/ 2018- 19/- | Assay 90.0 – 115.0% | Dissolution NLT 80% |
|-------------------------|---------|-----------------------------------|-------------|----------------------------|---------------------------------|---------|---------------|-----------------|---------------------|---------------------|
| 4.09.2018/0032 | | Pharmacy | | Tablets* | | | | | | |
| FAFT/03/04.09.2018/038 | Private | Kentons Ltd | Kisumu | Folitab Tablets | Nabiqasim Industries (Pvt.) Ltd | F02077 | 256 | 348 | 100.2% | 109% |
| FAFT/04/05.09.2018/024 | Private | Makadara Chemist | Mombasa | Folic Acid Tablets BP | Cosmos Limited | 80920 | 255 | 347 | 100.3% | 101% |
| FAFT/08/04.09.2018/004 | Private | Al-Qudus Pharmaceuticals | Garissa | Folic Acid Tablets 5 mg | Surepharm Services Ltd | 56189 | 254 | 343 | 100.8% | 104% |
| FAFT/06/04.09.2018/0008 | Public | Kinna Health Centre | Isiolo | Folic Acid Tablets | Biodeal Laboratories Ltd | 0417116 | 253 | 346 | 109.5% | 114% |
| FAFT/07/07.09.2018/024 | Public | Nyeri Provincial General Hospital | Nyeri | Folic Acid 5 mg Tablets BP | Laboratory & Allied Limited | 65372 | 252 | 345 | 96.5% | 113% |
| FAFT/02/05.09.2018/008 | Private | Pilot Pharmaceuticals | Uasin-Gishu | Folic Acid 5 mg Tablets BP | Regal Pharmaceuticals Ltd | 180286 | 251 | 344 | 108.2% | 104% |
| FEFT/03/03.09.2018/014 | Public | Kisumu County Hospital | Kisumu | Ferrolic - LF® Tablets | Laboratory & Allied Limited | 70719 | 260 | 379 | 122.9% ² | 121% |
| FEFT/01/10.09.2018/099 | Private | Nila Pharmaceuticals | Nairobi | Softron Tablets | Not Indicated | T041 | 258 | 377 | 131.8% ² | 139% |
| FEFT/01/04.09.2018/036 | Public | Kenya Medical Supplies Authority | Nairobi | Ferrolic - LF® Tablets | Laboratory & Allied Limited | 71624 | 259 | 378 | 119.0% ² | 121% |

²Failed Assay test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All the seven (7) samples of single component folic acid tablets complied with the requirements for the tests performed.

Three (3) out of five (5) of the FDC samples failed to comply with the specification for contents of folic acid. Notably, all three non-compliant samples contained more than the specified amount of folic acid. In addition, one of the non-compliant samples (Softron) did not have details of the manufacturer.

3.4.3.9 Glibenclamide Tablets

All the thirteen (13) samples of Glibenclamide tablets complied with the requirements for the tests performed.

Table 21: Glibenclamide tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 95.0 – 105.0% | Dissolution NLT 70% |
|--------------------------------|---------|------------------------------------|-------------|-------------------|--|---------|--------------|----------------|---------------------|---------------------|
| GLBT/03/03.09.2018/004 | Public | Nyanza Provincial General Hospital | Kisumu | Nogluc® Tablets | Cosmos Limited | 60840 | 250 | 329 | 97.5% | 102% |
| GLBT/07/10.09.2018/061 | Private | Mbeti Pharmacy | Embu | Gliboral® Tablets | A. Menarini Manufacturing Logistics And Services S.r.l | 544A | 249 | 328 | 95.6% | 100% |
| GLBT/06/06.09.2018/0017 | Public | Isiolo District Hospital | Isiolo | Glimide® Tablets | Laboratory & Allied Ltd | 65715 | 248 | 327 | 97.4% | 102% |
| GLBT/05/06.09.2018/027 | Public | Machakos Level 5 Hospital | Machakos | Glibetics Tablets | Flamingo Pharmaceutica ls Limited | J627 | 247 | 326 | 98.1% | 103% |
| GLBT/01/06.09.2018/065 | Private | Surgipharm Ltd | Nairobi | Daonil® Tablets | Aventis Pharma (India) Ltd. (Fab. Verna) | 7G029A | 246 | 325 | 98.8% | 104% |
| GLBT/01/03.09.2018/001 | Public | Kenya Medical Supplies Authority | Nairobi | Nogluc® Tablets | Cosmos Limited | 80842 | 245 | 324 | 96.5% | 102% |
| GLBT/01/10.09.2018/142 | Private | Zen Pharmaceuticals – Prestige | Nairobi | Daonil® Tablets | Not Indicated (Made in India) | 7NG005 | 244 | 323 | 99.9% | 105% |
| GLBT/08/07.09.2018/043 | Private | Nunguni Chemists Ltd | Kitui | Daonil® Tablets | Sanofi Aventis Egypt S.A.E. ^a | 7EG015 | 243 | 322 | 96.1% | 101% |
| GLBT/02/ | Private | Lifecare | Uasin-Gishu | Daonil® | Sanofi Aventis | 7EG015 | 242 | 321 | 97.8% | 104% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 95.0 – 105.0% | Dissolution NLT 70% |
|--------------------------------|---------|----------------------------|--------|-------------------|--|---------|--------------|----------------|---------------------|---------------------|
| 08.09.2018/059 | | Pharmaceuti cals | | Tablets | Egypt S.A.E. ^a | | | | | |
| GLBT/04/07.09.2018/048 | Private | Old Madaraka Chemist | Kilifi | Daonil® Tablets | Aventis Pharma (India) Ltd. (Fab. Verna) | 7G029A | 241 | 320 | 96.9% | 102% |
| GLBT/03/04.09.2018/049 | Private | Kentons Ltd | Kisumu | Glimide® Tablets | Laboratory & Allied Ltd | 71129 | 240 | 319 | 98.2% | 103% |
| GLBT/07/06.09.2018/019 | Public | Karatina District Hospital | Nyeri | Nogluc® Tablets | Cosmos Limited | 71242 | 239 | 318 | 98.7% | 102% |
| GLBT/09/03.09.2018/0018 | Private | Transwide Pharmaceuti cals | Nakuru | Gliboral® Tablets | A. Menarini Manufacturing Logistics and Services S.r.l | 544A | 238 | 317 | 95.7% | 98% |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

3.4.3.10 Hydrochlorothiazide Tablets

All fifteen (15) samples of hydrochlorothiazide tablets complied with the requirements for the tests performed

Table 22: Hydrochlorothiazide tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 65% |
|--------------------------------|-------------|---|----------|---------------------------------|----------------|---------|--------------|----------------|---------------------|---------------------|
| HCT5/03/05.09.2018/066 | Private | Scorpion Pharmacy | Busia | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80050 | 263 | 354 | 97.4% | 106% |
| HCT5/06/10.09.2018/066 | Faith-Based | St Theresa Kiirua Hospital (Kiirua) | Meru | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80049A | 264 | 355 | 98.5% | 108% |
| HCT5/06/07.09.2018/046 | Private | Sage Pharmacy | Isiolo | Hydrochloro thiazide Tablets BP | Cosmos Limited | 70806 | 265 | 356 | 92.1% | 104% |
| HCTZ/03/04.09.2018/025 | Public | Muhoroni Sub-District Hospital | Kisumu | Hydrochloro thiazide Tablets BP | Cosmos Limited | 60606 | 266 | 357 | 98.7% | 89% |
| HCTZ5/05/06.09.2018/030 | Public | Machakos Level 5 Hospital | Machakos | Hydrochloro thiazide Tablets BP | Cosmos Limited | 51596 | 267 | 358 | 97.9% | 78% |
| HCTZ/07/07.09.2018/035 | Public | Nyeri Provincial General Hospital (PGH) | Nyeri | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80048 | 268 | 359 | 97.8% | 100% |
| HCTZ/07/10.09.2018/057 | Private | Mbeti Pharmacy | Embu | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80052 | 269 | 360 | 99.7% | 99% |
| HCTZ2/05/07.09.2018/057 | Private | Lenana Pharmaceuti cals Ltd | Kajiado | Hydrochloro thiazide Tablets BP | Cosmos Limited | 70444 | 270 | 361 | 97.6% | 100% |
| HCT2/04/07.09.2018/059 | Private | Reenland Pharmacy | Kilifi | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80906 | 271 | 362 | 99.1% | 106% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 65% |
|--------------------------------|---------|----------------------------------|-------------|---------------------------------|-------------------------|---------|--------------|----------------|---------------------|---------------------|
| HCTZ/02/05.09.2018/009 | Private | Pilot Pharmaceuticals | Uasin-Gishu | Hydrochloro thiazide Tablets BP | Cosmos Limited | 71001 | 272 | 363 | 98.1% | 95% |
| HCTZ/01/10.09.2018/108 | Private | Transchem | Nairobi | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80907 | 273 | 364 | 98.4% | 94% |
| HCTZ/08/06.09.2018/030 | Private | Medina Pharmacy Limited | Garissa | Hydrochloro thiazide Tablets BP | Cosmos Limited | 70805 | 274 | 365 | 98.7% | 102% |
| HCTZ/01/07.09.2018/071 | Public | Kenyatta National Hospital | Nairobi | Hydrochloro thiazide Tablets BP | Cosmos Limited | 71003 | 275 | 366 | 98.0% | 105% |
| HCTZ/09/03.09.2018/0007 | Private | Transwide Pharmaceuticals | Nakuru | Hymet® 50 mg Tablets | Laboratory & Allied Ltd | 67499 | 276 | 367 | 90.8% | 90% |
| HCTZ/01/04.09.2018/045 | Public | Kenya Medical Supplies Authority | Nairobi | Hydrochloro thiazide Tablets BP | Cosmos Limited | 80846 | 277 | 368 | 97.3% | 90% |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

3.4.3.11 Levonorgestrel

All twelve (12) samples of levonorgestrel tablets complied with the requirements for the tests performed.

Table 23: Levonorgestrel tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 70% |
|-------------------------|---------|----------------------------|---------|--------------------------------------|---------------------------------------|-----------|--------------|----------------|---------------------|---------------------|
| LGNT/08/06.09.2018/036 | Private | Makkah Pharmaceuticals Ltd | Garissa | P2 Levonorgestrel Tablets BP 0.75 mg | Mylan Laboratories Ltd | LT715 | 377 | 313 | 96.6% | 90% |
| LGNT/01/10.09.2018/096 | Private | Nila Pharmaceuticals | Nairobi | Ecee 2 Tablets | Not Indicated | S703570 | 376 | 312 | 91.3% | 91% |
| LGNT/09/06.09.2018/0065 | Private | Agape Pharmaceuticals | Narok | Ecee 2 Tablets | Not Indicated | S703378 | 375 | 375 | 92.4% | 95% |
| LGNT/03/05.09.2018/054 | Private | Scorpion Pharmacy | Busia | Choice - 72 Tablets BP | Synokem Pharmaceuticals Ltd | E7SHLT002 | 374 | 310 | 99.1% | 98% |
| LGNT/04/12.09.2018/091 | Private | Eldohosp Pharmaceuticals | Mombasa | Truston - 2 TM Tablets | Not Indicated | VT 17099 | 373 | 309 | 106.4% | 104% |
| LGNT/04/12.09.2018/089 | Private | Eldohosp Pharmaceuticals | Mombasa | Option - 2 Tablets | Corona Remedies Pvt. Ltd | EKE-001 | 372 | 308 | 99.8% | 98% |
| LGNT/01/10.09.2018/093 | Private | Nila Pharmaceuticals | Nairobi | Preyniloc [®] Tablets | Combitic Global Caplet Pvt. Ltd | PGN-11 | 371 | 307 | 95.2% | 96% |
| LGNT/03/05.09.2018/060 | Private | Scorpion Pharmacy | Busia | Postinor [®] - 2 Tablets | Gedeon Richter Plc | T83299C | 370 | 306 | 101.2% | 87% |
| LGNT/01/10.09.2018/120 | Private | Transchem | Nairobi | Levo - 72 Tablets | West - Coast Pharmaceutical Works Ltd | WH18024 | 369 | 305 | 106.5% | 98% |

| | | | | | | | | | | |
|---|---------|---------------------------------|-------------|--|---------------------------------------|----------|-----|-----|--------|------|
| LGN5/04/0 3.09.2018/ 011 | Private | Shifa Chemist | Mombasa | L-Gest Tablets | Corona Remedies Pvt. Ltd | EX-499 | 368 | 304 | 101.2% | 97% |
| LGN5/01/0 5.09.2018/ 059 | Private | Harleys Pharmaceuti cals | Nairobi | Emcon 1 [®] Tablets | Reneta Limited | 18006 | 367 | 303 | 100.1% | 100% |
| LGN5/02/0 6.09.2018/ 023 | Private | Eldohosp Pharmaceuti cals | Uasin-Gishu | Lydia [™] Postpil Tablets | Naari Pharma Private Limited | HT17023B | 366 | 302 | 101.0% | 102% |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

3.4.3.12 Metformin tablets

All fourteen (14) samples of metformin tablets complied with the requirements for the tests performed.

Table 24: Metformin tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809 - | CAN/ 2018-19/- | Assay 90 - 110% | Dissolution NLT 85% |
|--------------------------------|-------------|------------------------------------|-------------|--|----------------------------------|---------|---------------|----------------|-----------------|---------------------|
| MTF8/01/03.09.2018/014 | Public | Kenya Medical Supplies Authority | Nairobi | Glucodeal Tablets | Biodeal Laboratories Ltd | 518018 | 224 | 178 | 96.1% | 101% |
| MTF8/02/05.09.2018/003 | Private | Pilot Pharmaceuticals | Uasin Gishu | Glucomet Film Coated Tablets BP 850 mg | Cosmos Limited | 71145 | 222 | 176 | 99.8% | 102% |
| MTF5/06/07.09.2018/038 | Faith-Based | Matercare Maternity Hospital | Isiolo | Glucomet Film Coated Tablets BP 500 mg | Cosmos Limited | 70789 | 213 | 167 | 99.9% | 99% |
| MTF5/07/07.09.2018/031 | Public | Nyeri Provincial General Hospital | Nyeri | Metmin 500 mg Tablets | Dawa Limited | 1805111 | 214 | 168 | 101.6 % | 101% |
| MTF8/07/10.09.2018/067 | Private | Mbeti Pharmacy | Embu | Metformin Denk 850 Tablets | Denk Pharma GmbH & Co. KG | 18504 | 223 | 177 | 98.0% | 101% |
| MTF5/01/10.09.2018/136 | Private | Generics Africa | Nairobi | Metformin Denk 500 Tablets | Denk Pharma GmbH & Co. KG | 9G8 | 220 | 174 | 95.5% | 102% |
| MTF5/01/05.09.2018/052 | Private | Harleys Pharmaceuticals | Nairobi | Gludown 500 Tablets | Laboratory & Allied Ltd | 71504 | 219 | 173 | 99.9% | 100% |
| MTF8/08/05.09.2018/015 | Private | Ummah Pharmacy | Garissa | Glucophage 850 mg Film-Coated Tablets | Nkunzi Pharmaceuticals (Pty) Ltd | C17020 | 226 | 180 | 96.2% | 90% |
| MTF8/09/04.09.2018/0025 | Private | Elim Central Pharmacy | Nakuru | Glucophage 850 mg Film-Coated Tablets | Nkunzi Pharmaceuticals (Pty) Ltd | C16078 | 225 | 179 | 95.3% | 97% |
| MTF5/03/03.09.2018/006 | Public | Nyanza Provincial General Hospital | Kisumu | Glucophage 500 mg Tablets | Nkunzi Pharmaceuticals (Pty) Ltd | C16024 | 217 | 171 | 95.3% | 97% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809 - | CAN/ 2018-19/- | Assay 90 - 110% | Dissolution NLT 85% |
|-------------------------------|---------|----------------------------|----------|----------------------------|---|---------|---------------|----------------|-----------------|---------------------|
| MTF8/05/04.09.2018/010 | Public | Kangundo District Hospital | Machakos | Diaphage - 850 Tablets | Universal Corporation Ltd | 5803515 | 221 | 175 | 95.8% | 107% |
| MTF5/01/07.09.2018/073 | Public | Kenyatta National Hospital | Nairobi | Asformin Tablets BP 500 mg | Astra Lifecare (India) Pvt. Ltd | 006 | 218 | 172 | 95.9% | 97% |
| MTF5/04/03.09.2018/008 | Private | Shifa Chemist | Mombasa | Metfil Tablets BP 500 mg | Fourrts (India) Laboratories Pvt. Limited | E2426 | 215 | 169 | 101.0 % | 95% |
| MTF5/03/06.09.2018/081 | Private | Victoria Healthcare | Kisumu | Sukarmin 500 mg Tablets* | Biopharma Limited | BPL690 | 216 | 170 | 97.6% | 95% |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

3.4.3.13 Paracetamol Tablets

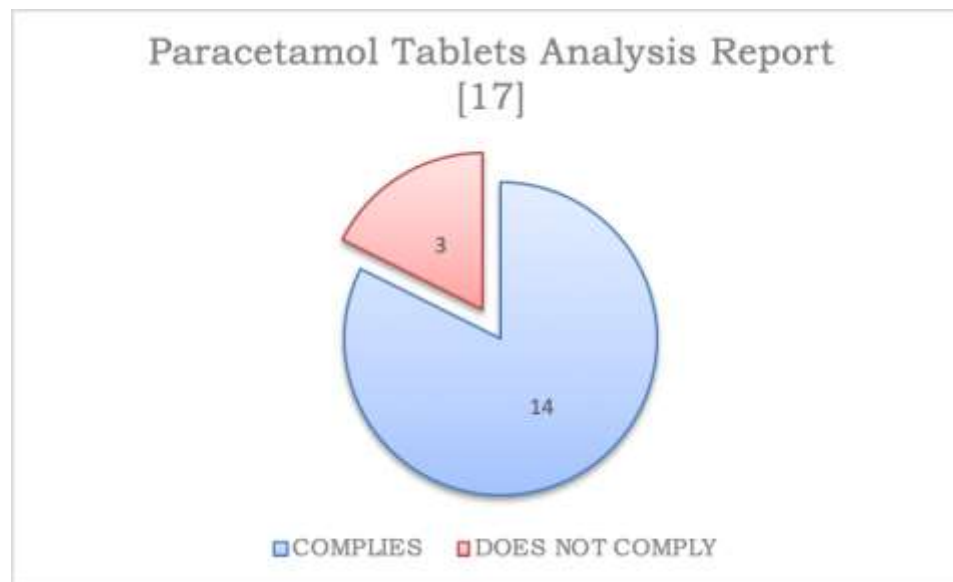


Figure 22: Compliance results for Paracetamol tablets

Table 25: Paracetamol tablets sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|-------------------------------|---------|--------------------------|-------------|-----------------|-----------------------------------|---------|--------------|----------------|---------------------|---------------------|
| PCMT/06/06.09.2018/026 | Public | Isiolo District Hospital | Isiolo | Milzor Tablets* | Milan Laboratories India Pvt. Ltd | MG17408 | 160 | 117 | 92.4% | 98% |
| PCMT/02/07.09.2018/033 | Private | Sarara Chemist | Trans Nzoia | Paratal Tablets | Laboratory & Allied Ltd | 72173 | 158 | 146 | 95.7% | 95% |
| PCMT/01/03.09.2018/017 | Public | Kenya Medical Supplies | Nairobi | Cetamol Tablets | Regal Pharmaceutica ls Ltd | 181371 | 157 | 116 | 92.8% | 98% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------------|-------------|--------------------------------|------------|-------------------------|---|---------|--------------|----------------|---------------------|---------------------|
| | | Authority | | | | | | | | |
| PCMT/02/06.09.2018/017 | Private | Eldohosp Pharmaceuticals | UasinGishu | Asmol Tablets | Astra Lifecare (India) Pvt. Ltd | 2233 | 156 | 141 | 92.8% | 90% |
| PCMT/09/04.09.2018/0023 | Private | Elim Central Pharmacy | Nakuru | Caremol Tablets | Shanxi Xinyitong Pharmaceutical Co., Ltd | 171003 | 155 | 337 | 95.6% | 89% |
| PCMT/06/10.09.2018/061 | Faith-Based | St Theresa Kiirua Hospital | Meru | Fremol Tablets | Fredun Pharmaceuticals Ltd | FC814 | 154 | 140 | 93.0% | 89% |
| PCMT/04/10.09.2018/066 | Private | Azmon Pharmacy | Kilifi | Asmol Tablets | Astra Lifecare (India) Pvt. Ltd | 2232 | 153 | 99 | 93.1% | 93% |
| PCMT/04/05.09.2018/028 | Private | Makadara Chemist | Mombasa | Arcet Tablets | Hebei Jiheng (Group) Pharmaceutical Co. Ltd | 180457 | 152 | 98 | 91.8% | 95% |
| PCMT/03/04.09.2018/033 | Public | Ahero County Hospital | Kisumu | Paratal Tablets | Laboratory & Allied Ltd | 71228 | 151 | 145 | 91.9% | 85% |
| PCMT/03/05.09.2018/057 | Private | Scorpion Pharmacy | Busia | Panadol Advance Tablets | Glaxosmithkline Knockbrack | X061RL | 150 | 144 | 93.3% | 94% |
| PCMT/01/10.09.2018/147 | Private | Zen Pharmaceuticals - Prestige | Nairobi | Panadol Advance Tablets | Glaxosmithkline Knockbrack | X062RN | 148 | 139 | 92.4% | 94% |
| PCMT/07/05.09.2018/006 | Public | Mukurweini District Hospital | Nyeri | Cetamol Tablets | Regal Pharmaceuticals Ltd | 151948 | 146 | 115 | 90.9% | 89% |
| PMCT/05/07.09.2018/036 | Faith-Based | Bishop Kioko Catholic Hospital | Machakos | Arcet Tablets | Hebei Jiheng (Group) Pharmaceutical Co. Ltd | 180456 | 145 | 113 | 91.2% | 95% |
| PCMT/08/ | Private | Nunguni | Kitui | Dolomol | Lincoln | SC6001 | 144 | 114 | 92.1% | 93% |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------------|---------|----------------------------------|---------|-----------------|----------------------------|---------|--------------|----------------|---------------------|---------------------|
| 07.09.2018/053 | | Chemists Ltd | | Tablets | Pharmaceuticals Ltd | | | | | |
| PCMT/09/06.09.2018/0066 | Private | Agape Pharmaceuticals | Narok | Jotonol Tablets | Benmed Pharmaceuticals Ltd | 218 | 159 | 142 | 93.5% | 28% ¹ |
| PCMT/07/10.09.2018/048 | Private | Itabua Chemist | Embu | Fremol Tablets | Fredun Pharmaceuticals Ltd | FD820 | 149 | 333 | 97.0% ⁴ | 87% |
| PCMT/01/03.09.2018/008 | Public | Kenya Medical Supplies Authority | Nairobi | Biomol Tablets | Biodeal Laboratories Ltd | 318077 | 147 | 334 | 96.5% ⁴ | 92% |

¹Failed Dissolution test,⁴Failed Uniformity of Weight test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

Fourteen (14) out of the seventeen (17) samples complied with all the test parameters. All the samples tested complied with the requirements for identity and content of active ingredient (Assay). One (1) sample did not comply with the requirements for dissolution. Additionally, two (2) samples failed to comply with uniformity of weight requirements despite meeting the specifications for all other critical tests.

3.4.3.14 Paracetamol Oral Suspension

Table 26: Paracetamol oral suspension sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | pH 4.0 – 6.9 |
|------------------------|-------------|------------------------------------|-------------|------------------------------|------------------------------|---------|--------------|----------------|---------------------|--------------|
| PCMS/06/10.09.2018/070 | Faith-Based | St Theresa Kiirua Hospital | Meru | Elymol Paediatric Suspension | Elys Chemical Industries Ltd | 8E130 | 176 | 101 | 99.7% | 5.9 |
| PCMS/01/10.09.2018/090 | Private | Nila Pharmaceuticals | Nairobi | Pamol Suspension | Comet Healthcare Ltd | 180308 | 175 | 108 | 95.7% | 5.6 |
| PCMS/07/10.09.2018/059 | Private | Mbeti Pharmacy | Embu | Calpol Paediatric Suspension | GlaxoSmithkline Limited | Y0325D | 173 | 109 | 92.9% | 5.1 |
| PCMS/03/06.09.2018/084 | Private | Victoria Healthcare | Kisumu | Pyremol Oral Suspension | Concepts (Africa) Limited | H0820 | 172 | 100 | 95.6% | 5.4 |
| PCMS/04/12.09.2018/079 | Private | Surgipharm Ltd Mombasa | Mombasa | Panadol Suspension | Farmaclair Herouville | S103 | 171 | 110 | 95.9% | 5.2 |
| PCMS/08/08.09.2018/063 | Private | Stera Pharmacy | Kitui | Calpol Paediatric Suspension | Glaxosmithkline Limited | Y032SD | 170 | 315 | 91.2% | 5.2 |
| PCMS/08/06.09.2018/016 | Private | Medina Pharmacy Limited | Garissa | Curamol Suspension | Dawa Limited | 1805148 | 169 | 143 | 96.8% | 5.1 |
| PCMS/02/05.09.2018/001 | Private | Pilot Pharmaceuticals | Uasin-Gishu | Painil Suspension | Njimia (K) Limited | 19108 | 168 | 335 | 95.3% | 5.8 |
| PCMS/09/03.09.2018/001 | Private | Transwide Pharmaceuticals | Nakuru | Pyremol Suspension | Concepts (Africa) Limited | A0626 | 167 | 111 | 92.7% | 4.9 |
| PCMS/03/03.09.2018/001 | Public | Nyanza Provincial General Hospital | Kisumu | Curamol Suspension | Dawa Limited | 1611182 | 166 | 112 | 100.3% | 5.0 |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | pH 4.0 – 6.9 |
|------------------------|---------|----------------------------------|---------|----------------------|----------------------------|---------|--------------|----------------|---------------------|--------------|
| PCMS/05/07.09.2018/056 | Private | Lenana Pharmaceuticals Ltd | Kajiado | Painil Suspension | Njimia (K) Limited | 27608 | 165 | 340 | 93.9% | 5.8 |
| PCMS/01/10.09.2018/129 | Private | Transchem | Nairobi | Betamol Suspension | Sphinx Pharmaceuticals Ltd | 02079P | 164 | 118 | 101.3% | 5.3 |
| PCMS/04/07.09.2018/049 | Private | Old Madaraka Chemist | Kilifi | Jotonol Suspension | Benmed Pharmaceuticals Ltd | 01218 | 163 | 338 | 91.2% | 5.8 |
| PCMS/01/03.09.2018/013 | Public | Kenya Medical Supplies Authority | Nairobi | Curamol Suspension | Dawa Limited | 1804194 | 162 | 107 | 92.3% | 5.1 |
| PCMS/05/07.09.2018/060 | Private | Lenana Pharmaceuticals Ltd | Kajiado | Toto-Mol® Suspension | Laboratory & Allied Ltd | 70455 | 161 | 336 | 96.2% | 4.9 |
| PCMS/01/10.09.2018/134 | Private | Generics Africa | Nairobi | Parol Suspension | Atabay İLAÇ | 180277 | 174 | 339 | 99.7% | 5.9 |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All the sixteen (16) paracetamol oral suspensions complied with the tests carried out.

3.4.3.15 Sildenafil tablets and soft gel

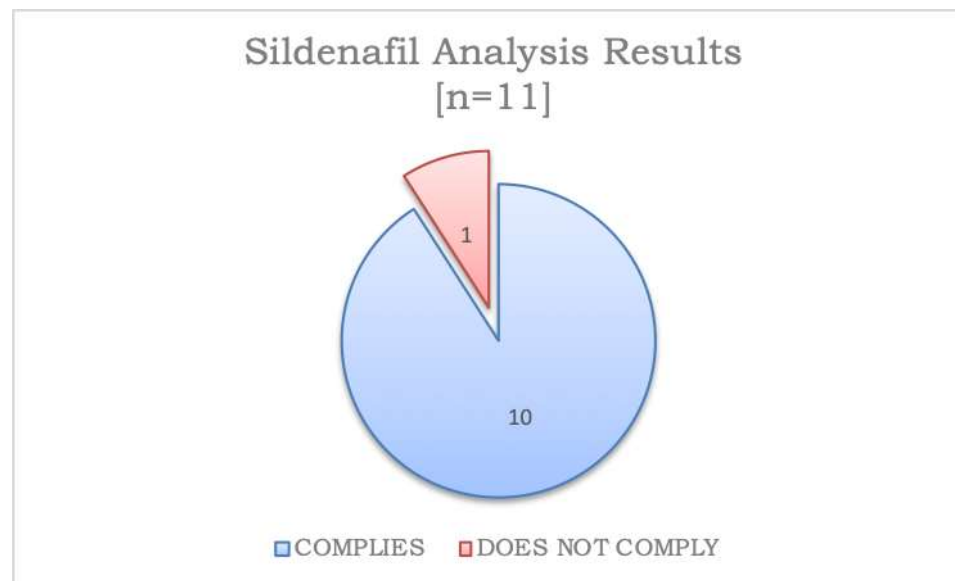


Figure 23: Compliance results for Sildenafil

Table 27: Sildenafil sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Assay 90.0 – 110.0% | Dissolution NLT 85% |
|--------------------------------|---------|-----------------------|---------|--------------------|-------------------------------|---------|--------------|----------------|---------------------|---------------------|
| SDF1/09/06.09.2018/0069 | Private | Agape Pharmaceuticals | Narok | Negax 100 Tablets | Ratnamani Healthcare Pvt. Ltd | CT674 | 235 | 197 | 99.1% | 102% |
| SDF1/03/04.09.2018/050 | Private | Kentons Ltd | Kisumu | Zedgra 100 Tablets | Zota Healthcare Ltd | ZG27001 | 236 | 198 | 94.6% | 95% |
| SDF1/01/10.09.2018/ | Private | Transchem | Nairobi | MTM - 100 Tablets | Mepro Pharmaceutic | 2028 | 234 | 199 | 97.4% | 101% |

| | | | | | | | | | | |
|--------------------------------|---------|--------------------------------|-------------|----------------------|------------------------------------|----------|-----|-----|----------------------|------------------|
| 118 | | | | | als Limited | | | | | |
| SDF1/04/07.09.2018/058 | Private | Reenland Pharmacy | Kilifi | Mygra - 100 Tablets | S. Kant Healthcare Ltd | SC7004 | 233 | 200 | 94.9% | 102% |
| SDF5/09/06.09.2018/0049 | Private | Jaslim Pharmacy | Narok | Ega - 50 Tablets | Osaka Pharmaceuticals Pvt. Ltd | 8E031 | 232 | 201 | 92.9% | 84% |
| SDF5/01/09.09.2018/085 | Private | Rafiki Pharmaceuticals | Nairobi | Powerra - 50 Tablets | Umedica Laboratories Pvt. Ltd | MB603 | 231 | 202 | 100.5% | 101% |
| SDF5/03/05.09.2018/056 | Private | Scorpion Pharmacy | Busia | Nelgra - 50 Tablets | Universal Corporation Ltd | 5801666 | 230 | 203 | 98.4% | 100% |
| SDF5/02/07.09.2018/042 | Private | Sarara Chemist | Trans Nzoia | Gomore - 50 Tablets | Zim Laboratories Limited | FY98M601 | 229 | 204 | 102.9% | 95% |
| SDF5/01/10.09.2018/154 | Private | Zen Pharmaceuticals - Prestige | Nairobi | Viagra 50 mg Tablets | Pfizer PGM | B044506 | 228 | 205 | 98.0% | 100% |
| SDF5/04/07.09.2018/0042 | Private | Old Madaraka Chemist | Kilifi | Zegra - 50 Tablets | Benmed Pharmaceuticals Ltd | T00418 | 227 | 316 | 78.3% ^{2,4} | 82% ^c |
| SDF1/08/07.09.2018/051 | Private | Nunguni Chemists Ltd | Kitui | Luvmax 100 Softgels | Gujarat Liqui Pharmacaps Pvt. Ltd. | G170497 | 237 | 353 | 98.5% | - |

²Failed Assay test, ⁴Failed Uniformity of Weight test, ^cPassed S₂ dissolution test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All but one (1) of the eleven (11) sildenafil samples complied with the tests carried out. The non-compliant sample failed on content of sildenafil and uniformity of weight.

3.4.3.16 Male Latex Condoms

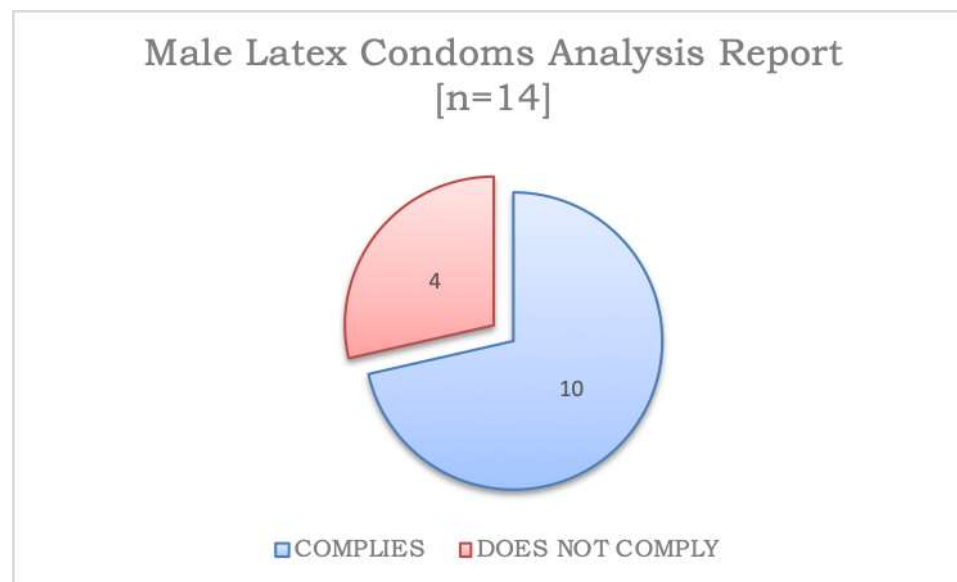


Figure 24: Compliance results for male latex condoms

Table 28: Male Latex Condom sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Analysis Results |
|---|---------|-------------------------|---------|---------------------------|---------------------------------------|------------|--------------|----------------|------------------|
| CDML/01/05 .09.2018/05 6 | Private | Harleys Pharmaceuticals | Nairobi | Durex® Extra Safe Condoms | SSL International Plc | 1000407984 | 291 | 294 | COMPLIES |
| CDML/01/10 .09.2018/13 8 | Private | Generics Africa | Nairobi | Durex® Fetherlite Condoms | SSL Manufacturing (Thailand) Limited. | 1000374417 | 288 | 300 | COMPLIES |
| CDML/03/06 .09.2018/09 2 | Private | Victoria Healthcare | Kisumu | Trust™ Ribbed Condoms | Cupid Limited | RD1801 | 285 | 298 | COMPLIES |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Analysis Results |
|---------------------------------|---------|--------------------------------|-------------|------------------------------|----------------------------|------------|--------------|----------------|------------------------------|
| CDML/04/03 .09.2018/00 1 | Private | Shifa Chemist | Mombasa | Trust™ Classic Condoms | Karex Industries SDN BHD | 17N4347 | 284 | 297 | COMPLIES |
| CDML/03/06 .09.2018/09 1 | Private | Victoria Healthcare | Kisumu | Trust™ Studded Condoms | Guilin Zizhu Latex Co. Ltd | 774012 | 283 | 296 | COMPLIES |
| CDML/09/04 .09.2018/00 38 | Private | Supreme Pharmacy | Nakuru | Trust™ Studded Condoms | Guilin Zizhu Latex Co. Ltd | 774011 | 282 | 291 | COMPLIES |
| CDML/08/08 .09.2018/06 2 | Private | Stera Pharmacy | Kitui | Kiss Classic Condoms | Cupid Limited | Pk1728 | 281 | 295 | COMPLIES |
| CDML/08/08 .09.2017/07 0 | Private | Stera Pharmacy | Kitui | Trust™ Classic Condoms | Cupid Limited | PB1830 | 280 | 290 | COMPLIES |
| CDML/02/08 .09.2018/04 7 | Private | Northpharm Company Limited | Uasin-Gishu | Trust™ Studded Condoms | Guilin Zizhu Latex Co. Ltd | 774015 | 279 | 289 | COMPLIES |
| CDML/02/08 .09.2018/04 8 | Private | Northpharm Company Limited | Uasin-Gishu | Leo Premium Condoms | Cupid Limited | DG 1601 | 278 | 288 | COMPLIES |
| CDML/04/12 .09.2018/08 2 | Private | Surgipharm Ltd Mombasa | Mombasa | Fiesta Stamina Condoms | Cupid Limited | DL1608 | 290 | 293 | DOES NOT COMPLY ⁵ |
| CDML/01/10 .09.2018/15 7 | Private | Zen Pharmaceuticals - Prestige | Nairobi | Rough Rider® Studded Condoms | Ansell Healthcare Europe | 1509031616 | 289 | 301 | DOES NOT COMPLY ⁶ |
| CDML/04/12 .09.2018/08 0 | Private | Surgipharm Ltd Mombasa | Mombasa | Fiesta Big Black Condoms | Cupid Limited | PL1625 | 287 | 292 | DOES NOT COMPLY ⁷ |
| CDML/01/10 .09.2018/10 5 | Private | Nila Pharmaceuticals | Nairobi | Moods® Ultrathin Condoms | HLL Lifecare Limited | L45UT009 | 286 | 299 | DOES NOT COMPLY ⁵ |

⁵Failed Freedom from Holes test, ⁶Failed Width test, ⁷Failed Thickness test, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

Four (4) out of the fourteen (14) condom samples failed to comply with the test requirements:
Two (2) failed on the tests for freedom from holes, while another two (2) samples did not comply with the test requirements for dimensions (condom width and thickness, respectively).

3.4.3.17 Manual use syringes (5 mL)

Table 29: 5 mL syringe sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Batch or Lot No. | NDQA 201809- | CAN/ 2018-19/- | Analysis Results |
|--------------------------------|---------|------------------------------------|----------|--|---|------------------|--------------|----------------|------------------|
| SYR5/03/03.09.2018/008 | Public | Nyanza Provincial General Hospital | Kisumu | I-Care Syringes 5 mL with Needle | Jiangyin Nanquan Macromolecule Product Co., Ltd | 180301 | 346 | 277 | COMPLIES |
| SYR5/03/03.09.2018/011 | Public | Nyanza Provincial General Hospital | Kisumu | BD Solomed™ Syringe 5 mL | Becton Dickson S. A. | 1409156 | 345 | 276 | COMPLIES |
| SYR5/03/06.09.2018/088 | Private | Victoria Healthcare | Kisumu | Ritemed Disposable Syringe 5 mL | Bio-Med Healthcare Products Pvt | 0517259 | 344 | 275 | COMPLIES |
| SYR5/07/04.09.2018/0022 | Private | Elim Central Pharmacy | Nakuru | Kings™ Hypodermic Syringes without Needle 5 mL | Changzhou J.M Equipment Co., Ltd | 1707 | 343 | 274 | COMPLIES |
| SYR5/01/10.09.2018/106 | Private | Nila Pharmaceuticals | Nairobi | Vensor-Nd Disposable Syringe with Needle 5 mL | Not Indicated | 0518032 | 342 | 273 | COMPLIES |
| SYR5/01/07.09.2018/078 | Public | Kenyatta National Hospital | Nairobi | Kings™ Hypodermic Syringes Without Needle 5 mL | Changzhou J. M Equipment Co., Ltd | 1747 | 341 | 272 | COMPLIES |
| SYR5/05/06.09.2018/034 | Public | Machakos Level 5 Hospital | Machakos | SKB Sterile Syringes For Single Use 5 mL | Shanghai Channelmed Import & Export Co., Ltd | 20160815 | 340 | 271 | COMPLIES |
| SYR5/04/05.09.2018/036 | Private | Makadara Chemist | Mombasa | Vitalcare Disposable Syringe 5 mL | Jiangyin Nanquan Macromolecule | 171123 | 339 | 270 | COMPLIES |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Batch or Lot No. | NDQA 201809- | CAN/ 2018-19/- | Analysis Results |
|---|-------------|---|-------------|--|------------------------------|------------------|--------------|----------------|------------------|
| | | | | Without Needle | Product Co., Ltd | | | | |
| SYR5/06/1 0.09.2018/ 059 | Faith-Based | St Theresa Kiirua Hospital (Kiirua) | Meru | BD Discardit 11 Syringe 5 mL | Becton Dickinson S. A. | 1704187 | 338 | 269 | COMPLIES |
| SYR5/07/0 7.09.2018/ 039 | Public | Nyeri Provincial General Hospital (PGH) | Nyeri | BD Solomed™ Syringe 5 mL | Becton Dickinson S. A. | 1409156 | 337 | 268 | COMPLIES |
| SYR5/04/0 3.09.2018/ 004 | Private | Shifa Chemist | Mombasa | ABC® Single Use Syringe 5 mL | Revital Healthcare (EPZ) Ltd | 067118 | 336 | 267 | COMPLIES |
| SYR5/02/0 7.09.2018/ 035 | Private | Sarara Chemist | Trans Nzoia | ABC® Single Use Syringe 5 mL | Revital Healthcare (EPZ) Ltd | 077818 | 335 | 266 | COMPLIES |
| SYR5/01/0 4.09.2018/ 024 | Public | Kenya Medical Supplies Authority | Nairobi | RH Revital® Re-Use Prevention Syringe 5 mL | Revital Healthcare (EPZ) Ltd | 116517 | 334 | 265 | COMPLIES |
| SYR5/01/0 4.09.2018/ 023 | Public | Kenya Medical Supplies Authority | Nairobi | RH Revital® Re-Use Prevention Syringe 5 mL | Revital Healthcare (EPZ) Ltd | 1210117 | 333 | 264 | COMPLIES |
| SYR5/01/1 0.09.2018/ 149 | Private | Zen Pharmaceuticals - Prestige | Nairobi | ABC® Single Use Syringe 5 mL | Revital Healthcare (EPZ) Ltd | 062718 | 332 | 263 | COMPLIES |

NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All fifteen (15) samples of 5 mL manual use syringes complied with the requirements for the tests performed.

3.4.3.18 Manual Use Syringes (10 mL)

Table 30: 10 mL syringe sample details and test results

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Analysis Results |
|-----------------------------------|-------------|--------------------------------|----------|--|---|----------|--------------|----------------|------------------|
| SYR1/05 /07.09.2 018/047 | Faith-Based | Bishop Kioko Catholic Hospital | Machakos | Disposable Syringe Without Needle 10 mL | Yangzhou Goldenwell Import & Export Co., Ltd | 20171218 | 331 | 259 | COMPLIES |
| SYR1/03 /04.09.2 018/035 | Public | Ahero County Hospital | Kisumu | Nipro Syringe With Needle 10 mL | PT. Nipro Indonesia Jaya | 17C0307J | 330 | 262 | COMPLIES |
| SYR1/01 /05.09.2 018/057 | Private | Harleys Pharmaceuticals | Nairobi | Medimax 2 Parts Disposable Syringe 10 mL | Changzhou Kangfulai Medical Thing Co., Ltd. | 20180125 | 329 | 261 | COMPLIES |
| SYR1/07 /10.09.2 018/065 | Private | Mbeti Pharmacy | Embu | Disposable Syringe | Not Indicated | 20170601 | 328 | 260 | COMPLIES |
| SYR1/09 /06.09.2 018/006 7 | Private | Agape Pharmaceuticals | Narok | Safeway Sterile Hypodermic Syringes For Single Use 10 mL | Lifelong Meditech Limited | 101510W | 327 | 258 | COMPLIES |
| SYR1/08 /04.09.2 018/005 | Private | Al-Qudus Pharmaceuticals | Garissa | I-Care Disposable Syringe 10 mL Without Needle | Jiangyin Nanquan Macromolecule Product Co., Ltd | 180301 | 326 | 257 | COMPLIES |
| SYR1/04 /12.09.2 018/073 | Private | Surgipharm Ltd Mombasa | Mombasa | BD Discardit™ Ii Syringe 10 mL | Becton Dickson S. A. | 1802287 | 325 | 256 | COMPLIES |
| SYR1/06 | Public | Isiolo | Isiolo | RH Revital® | Revital | 128117 | 324 | 255 | COMPLIES |

| Sample Code | Sector | Name of Facility | County | Brand Name | Manufacturer | Lot No. | NDQA 201809- | CAN/ 2018-19/- | Analysis Results |
|------------------------------------|---------|----------------------------------|---------|---|------------------------------|---------|--------------|----------------|-----------------------|
| /06.09.2 018/003 0 | | District Hospital | | Re-Use Prevention Syringe 10 mL | Healthcare (EPZ) Ltd | | | | |
| SYR1/01/04.09.2 018/027 | Public | Kenya Medical Supplies Authority | Nairobi | RH Revital® Re-Use Prevention Syringe 10 mL | Revital Healthcare (EPZ) Ltd | 066218 | 322 | 253 | COMPLIES |
| SYR10/01/04.09.2018/026 | Public | Kenya Medical Supplies Authority | Nairobi | RH Revital® Re-Use Prevention Syringe 10 mL | Revital Healthcare (EPZ) Ltd | 070618 | 321 | 252 | COMPLIES |
| SYR1/03/05.09.2 018/073 | Private | Scorpion Pharmacy | Busia | DCK® Single Use Syringe 10 mL | Revital Healthcare (EPZ) Ltd | 075418 | 323 | 254 | COMPLIES ⁸ |

⁸One syringe was not graduated, NDQA= Analytical Reference number, CAN= Certificate of Analysis number

All eleven (11) samples of 10 mL manual use syringes complied with the requirements for the tests performed.

3.5 Relationship between non-compliant test results, storage conditions and registration status

The table below summarizes non-compliant test results with the details of facilities storage conditions and products registration status.

Table 31: The registration status, storage temperature and humidity of the non-compliant samples

| Sample Code | Facility | County | Brand Name | Manufacturer | Registered | Storage Temp Limit (°C) | Storage Temp (°C) | % RH | Analysis Results |
|-------------------------------|------------------------------------|-------------|--|--|------------|-------------------------|-------------------|------|-------------------------|
| AMXS/02/05.09.2018/013 | Pilot Pharmaceuticals | Uasin-Gishu | Labmox Oral Suspension 125 mg/ 5 mL BP | Laborate Pharmaceuticals India Ltd | Y | 30 | 24.8 | 54 | Failed Assay Test |
| FEFT/03/03.09.2018/014 | Kisumu County Hospital | Kisumu | Ferrollic - Lf® Tablets | Laboratory & Allied Limited | Y | 30 | 29 | 51 | Failed Assay Test |
| FEFT/01/04.09.2018/036 | Kenya Medical Supplies Authority | Nairobi | Ferrollic - Lf® Tablets | Laboratory & Allied Limited | Y | 30 | 26.5 | 49 | Failed Assay Test |
| ENP5/01/03.09.2018/006 | Kenya Medical Supplies Authority | Nairobi | Acepril-5® Tablets | Laboratory & Allied Ltd | Y | 30 | 26.5 | 49 | Failed Assay Test |
| ENP5/07/07.09.2018/033 | Nyeri Provincial General Hospital | Nyeri | Acepril-5® Tablets | Laboratory & Allied Ltd | Y | 30 | 22 | 59 | Failed Assay Test |
| ENP5/03/03.09.2018/005 | Nyanza Provincial General Hospital | Kisumu | Enacare Tablets | Shandong Shenglu Pharmaceutical Co., Ltd | Y | 30 | 22.3 | 48 | Failed Assay Test |
| ALBT/07/06.09.2018/017 | Karatina District Hospital | Nyeri | Wombit Tablets | Biodeal Laboratories Ltd | Y | 30 | 19.9 | 78 | Failed Dissolution Test |
| ALBT/06/08.09.2018/053 | Meru District Hospital | Meru | Wombit Tablets | Biodeal Laboratories Ltd | Y | 30 | 24.2 | 42 | Failed Dissolution Test |
| ALBT/05/07.09.2018/046 | Bishop Kioko Catholic Hospital | Machakos | Abz Tablets | Indoco Remedies Ltd | Y | 30 | 21.5 | 61 | Failed Dissolution Test |

| Sample Code | Facility | County | Brand Name | Manufacturer | Registered | Storage Temp Limit (°C) | Storage Temp (°C) | % RH | Analysis Results |
|--------------------------------|----------------------------------|-------------|--------------------------|--|------------|-------------------------|-------------------|------|--------------------------------|
| ALBT/01/04.09.2018/032 | Kenya Medical Supplies Authority | Nairobi | Wombit Tablets | Biodeal Laboratories Ltd | Y | 30 | 26.5 | 49 | Failed Dissolution Test |
| ALBT/01/04.09.2018/030 | Kenya Medical Supplies Authority | Nairobi | Wombit Tablets | Biodeal Laboratories Ltd | Y | 30 | 26.5 | 49 | Failed Dissolution Test |
| ALBT/08/07.09.2018/049 | Nunguni Chemists Ltd | Kitui | Almex® 400 Tablets | Square Pharmaceuticals Ltd | Y | 30 | 26.1 | 58 | Failed Dissolution Test |
| ABLT/02/06.09.2018/028 | Lifecare Pharmaceuticals | Uasin-Gishu | Abz Tablets | Indoco Remedies Ltd | Y | 25 | 23.7 | 55 | Failed Dissolution Test |
| CPR5/06/07.09.2018/034 | Matercare Maternity Hospital | Isiolo | Strox Tablets | Universal Corporation Ltd | Y | 30 | 27.2 | 45 | Failed Dissolution Test |
| CPR5/09/03.09.2018/0012 | Transwide Pharmaceuticals | Nakuru | Cipcina - 500 Tablets | Shandong Shenglu Pharmaceutical Co., Ltd | Y | 30 | 26.4 | 50 | Failed Dissolution Test |
| PCMT/09/06.09.2018/0066 | Agape Pharmaceuticals | Narok | Jotonol Tablets | Benmed Pharmaceuticals Ltd | Y | 30 | 24.1 | 57 | Failed Dissolution Test |
| AMXT/03/04.09.2018/026 | Muhoroni Sub-District Hospital | Kisumu | Kemoxyl® DT 250 Tablets | Laboratory & Allied Ltd | Y | 30 | 24 | 69 | Failed Dissolution Test |
| CDML/01/10.09.2018/105 | Nila Pharmaceuticals | Nairobi | Moods® Ultrathin Condoms | HLL Lifecare Limited | Y | Not Indicated | 26.1 | 59 | Failed Freedom from Holes Test |
| CDML/04/12.09.2018/082 | Surgipharm Ltd Mombasa | Mombasa | Fiesta Stamina Condoms | Cupid Limited | Y | Cool Dry Place | 25.8 | 45 | Failed Freedom from Holes Test |
| CDML/04/12.09.2018/080 | Surgipharm Ltd Mombasa | Mombasa | Fiesta Big Black Condoms | Cupid Limited | Y | Cool Dry Place | 25.8 | 45 | Failed Thickness Test |
| PCMT/07/10.09.2018 | Itabua Chemist | Embu | Fremol Tablets | Fredun Pharmaceuticals | Y | 30 | 25.7 | 65 | Failed Uniformity of |

| Sample Code | Facility | County | Brand Name | Manufacturer | Registered | Storage Temp Limit (°C) | Storage Temp (°C) | % RH | Analysis Results |
|--------------------------------|----------------------------------|---------|------------------------------|----------------------------|------------|-------------------------|-------------------|------|---|
| /048 | | | | Ltd | | | | | Weight |
| PCMT/01/03.09.2018/008 | Kenya Medical Supplies Authority | Nairobi | Biomol Tablets | Biodeal Laboratories Ltd | Y | 30 | 26.5 | 49 | Failed Uniformity of Weight |
| FEFT/01/10.09.2018/099 | Nila Pharmaceuticals | Nairobi | Softron Tablets | Not Indicated | Y | 25 | 26.1 | 59 | Failed Uniformity of Weight & Assay Tests |
| SDF5/04/07.09.2018/0042 | Old Madaraka Chemist | Kilifi | Zegra - 50 Tablets | Benmed Pharmaceuticals Ltd | Y | Not Indicated | 29.4 | 68 | Failed Uniformity of Weight & Assay Tests |
| CDML/01/10.09.2018/157 | Zen Pharmaceuticals - Prestige | Nairobi | Rough Rider® Studded Condoms | Ansell Healthcare Europe | Y | Room Temp | 23 | 51 | Failed Width Test |

Based on the results obtained, there is no obvious correlation between non-compliant test results and storage conditions and registration status. Only one sample stored outside recommended storage temperature failed to comply with the tests performed. However, in this case the facility temperature (26.1 °C) deviated marginally from the manufacturers recommended storage temperature (25 °C). It is highly unlikely the non-compliance was attributable to this.

4 CONCLUSION

A total of 785 health products and technologies samples were collected from 64 facilities spread across 17 counties. These comprised of 250 distinct registrable products of which 215 (86%) were found to be registered.

Among the samples collected, the storage temperature conditions were explicitly and unambiguously stated in 638, of which 83.1% were stored within manufacturers' recommended conditions, while 16.9% were stored outside the manufacturers' specifications. The remaining 147 samples did not have explicit manufacturers' storage specifications.

All of the 243 secondary samples that were subjected to laboratory analysis, complied with the test requirements for identification and pH (where applicable). Two hundred and fourteen (214) out of the 243 secondary samples that were subjected to laboratory testing complied with the entire test parameters evaluated, while 25 pharmaceutical products and 4 medical devices failed to comply with one or more of the test parameters.

5 RECOMMENDATIONS

- i) Pharmacy and Poisons Board to take regulatory actions against all substandard and unregistered products.
- ii) Regular post market surveillance should be implemented preferably jointly (involving, PPB, NQCL, KEMSA and MoH) at least twice yearly.
- iii) More emphasis should be put on PMS testing as opposed to pre-registration testing. This is based on the fact that all the substandard products were registered except one.
- iv) Batch release procedure should be established for the critical public health products e.g. condoms, gloves, syringes and needles.
- v) Market authorization holders should explicitly indicate the specific storage conditions (i.e appropriate storage temperature

ranges) for the products particularly for the medical devices.

- vi) Manufacturers should regularly check and implement the updates in pharmacopoeial and other relevant industry guidelines.
- vii) All premises that store health products should regularly monitor and keep records of the environmental conditions i.e temperature and humidity.
- viii) Testing of additional samples of products that exhibited high failure rates e.g. albendazole tablets that failed to comply with dissolution specification.
- ix) The results of the study should be disseminated to all the stakeholders.

6 ANNEXES

1.0 Sample Collection Form

Rapid Results Initiative Post Market Surveillance 2018

Sample Code #: _____

Transcribe the appropriate sample code in the following format: **Formulation code/ Team No / Date of Sampling/Sample ID** e.g. **AMXC/01/20.08.2018/001** (The last 3 digits represent the Sample ID with the first sample collected being 001, 2nd 002 etc.)

Origin of Sample

| | | | |
|----------------|--|--------------------------------------|--|
| Facility Name: | | Facility Code: (Mandatory) | |
|----------------|--|--------------------------------------|--|

Product Details

| | | | |
|--|--|--|--|
| Active Pharmaceutical Ingredient (API): e.g. Amoxicillin | | | |
| Brand (Trade 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. Novartis 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) | | | |
| Sample Cost (KES): | | | |

Please Note

Follow proper sampling procedures. This sample collection form should always be kept with the sample collected

2.0 Facility Form

| Rapid Results Initiative Post Market Surveillance 2018 | | | |
|--|--|----------------------------------|--|
| Facility Code (MANDATORY) | | | |
| County: | | | |
| Name of Facility: (Use name in MFL list if applicable) | | | |
| Sector of Facility (Public, Private, Informal) | | | |
| Type of Facility (Hospital, Health Center) | | | |
| Contact Person: (Name of respondent at facility) | | | |
| E-mail address of contact Person: | | Mobile number of contact person: | |
| Date samples were collected at this facility (e.g. 10. 09. 2018) | | | |
| Storage Temperature: (in area/ room where sample was picked e.g. 26.5° Celsius) | | | |
| % Relative Humidity: (in area/ room where sample was picked e.g. 56.5%) | | | |

3.0 List of pharmaceutical products and medical devices to be sampled and analyzed

| No. | International Non-Proprietary name (INN), Formulation and Strength | Quantity Required | Tests | Minimum Quantity |
|--------------------------------|--|-------------------|--|------------------|
| Pharmaceutical Products | | | | |
| 1. | Albendazole 400 mg Tablets | 100 tablets | Identification (ID), Weight Uniformity, Assay, Dissolution | 50 Tablets |
| 2. | Albendazole 400 mg/10 ml Suspension | 20 bottles | ID, Assay | 10 Bottles |
| 3. | Amoxicillin 250 mg capsules | 100 capsules | ID, Weight Uniformity, Assay, Dissolution | 50 Capsules |
| 4. | Amoxicillin 500 mg capsules | 100 capsules | ID, Weight Uniformity, Assay, Dissolution | 50 Capsules |
| 5. | Amoxicillin 250 mg Dispersible Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 Tablets |
| 6. | Amoxicillin 125 mg/5 ml Dry Suspension | 20 bottles | ID, Assay, pH | 10 Bottles |
| 7. | Amoxicillin 250 mg/5 ml Dry Suspension | 20 bottles | ID, Assay, pH | 10 Bottles |
| 8. | Ciprofloxacin 500 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 Tablets |
| 9. | Enalapril 5 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 Tablets |
| 10. | Enalapril 10 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 11. | Folic acid 5 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 12. | Folic acid/Ferrous Sulphate 5/200 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 13. | Glibenclamide 5 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 14. | Hydrochlorothiazide 25 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 15. | Levonorgestrel 0.75/1.5 mg Tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 16. | Herbal contraceptives | * | ID | |
| 17. | Metformin 500 mg tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 18. | Metformin 850 mg tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 19. | Paracetamol 500 mg tablets | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 20. | Paracetamol 120 mg/5 ml suspension (60/100ml) | 20 bottles | ID, assay, pH | 10 bottles |

| | | | | |
|------------------------|---|-------------|---|------------|
| 21. | Paracetamol 120 mg/5 ml suspension (bulk) | 2 bottles | ID, assay, pH | 1 bottle |
| 22. | Sildenafil 50 mg | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 23. | Sildenafil 100 mg | 100 tablets | ID, Weight Uniformity, Assay, Dissolution | 50 tablets |
| 24. | Herbal ED preparations | * | ID | |
| Medical devices | | | | |
| 25. | Condoms latex male | 1000 pcs | Inflation, dimensions, freedom from holes | 1000 pcs |
| 26. | 5 ml Manual use Syringes | 100 pcs | Plunger function test, pH | 50 pcs |
| 27. | 10 ml Manual use Syringes | 100 pcs | Plunger function test, pH | 50 pcs |

**The products were available in a variety of formulations; therefore the quantities were determined at the time of sample collection.*

4.0 List of formulation codes

| No. | International Non-Proprietary name (INN), Formulation and Strength | Code |
|--------------------------------|--|-------|
| Pharmaceutical Products | | |
| 1. | Albendazole 400 mg Tablets | ALBT |
| 2. | Albendazole 400 mg/10 ml Suspension | ALBS |
| 3. | Amoxicillin 250 mg Capsules | AMXC |
| 4. | Amoxicillin 500 mg Capsules | AMXC |
| 5. | Amoxicillin 250 mg DT | AMXT |
| 6. | Amoxicillin 125 mg/5 ml Dry Suspension | AMXS |
| 7. | Amoxicillin 250 mg/5 ml Dry Suspension | AMXS |
| 8. | Ciprofloxacin 250 mg Tablets | CPR2 |
| 9. | Ciprofloxacin 500 mg Tablets | CPR5 |
| 10. | Enalapril 5 mg Tablets | ENP5 |
| 11. | Enalapril 10 mg Tablets | ENP1 |
| 12. | Folic acid 5 mg Tablets | FAFT |
| 13. | Folic acid/ferrous sulphate 5/200 mg Tablets | FEFT |
| 14. | Glibenclamide 5 mg Tablets | GLBT |
| 15. | Hydrochlorothiazide 25 mg Tablets | HCT2 |
| 15. | Hydrochlorothiazide 50 mg Tablets | HCT5 |
| 16. | Levonorgestrel 0.75/1.5 mg Tablets | LGNT |
| 17. | Herbal contraceptives | HCNC |
| 18. | Metformin 500 mg Tablets | MTF5 |
| 19. | Metformin 850 mg Tablets | MTF8 |
| 20. | Paracetamol 500 mg Tablets | PCMT |
| 21. | Paracetamol 120 mg/5 ml Suspension (60/100ml) | PCMS |
| 22. | Paracetamol 120 mg/5 ml Suspension (bulk)* | PCMS |
| 23. | Sildenafil 50 mg Tablets | SDF5 |
| 24. | Sildenafil 100 mg Tablets | SDF1 |
| 25. | Herbal ED Preparations* | HEDP |
| Medical Devices | | |
| 26. | Male Latex Condoms | CDML |
| 27. | 5 mL Manual Use Syringe | SYR5 |
| 28. | 10 mL Manual Use Syringe | SYR10 |

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