Quality Control of Drugs: A Case of Erythromycin Tablets in Chemist Shops of Meru Town. Kenya

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Abstract
Erythromycin stearate has been used for long in treatment of infections caused by susceptible strains of the designated organisms in many diseases. Because of this widespread use of the drug, there is an equally increased demand for cheaper generic erythromycin stearate tablets, of which their potency remains uncertain and hence compromise health. Therefore, there is need to determine quality of drugs sold to the public. Chemist shops selling human medicine in Meru Town. Fifty (50) chemist shops selling human medicine in Meru Town. The objective is to analyze erythromycin tablets for their quality performance by determining their potency through microbiological assay, disintegration time test and friability test. This was analytical study design. The samples of erythromycin tablets from selected manufacturers were bought from sampled chemists in Meru Town and analysed in the laboratory in order to determine their quality. All the samples examined passed the disintegration time test; friability test except microbiological assay. Perhaps, this may be due to faulty quality assurance and control during the process of manufacture and storage. There is need for sustained market surveillance of erythromycin tablets to ensure quality standards are maintained. Also further research should be done in order to establish the quality of other drugs in the market.

Keywords: quality control; microbiological assay: disintegration time test; friability test.

INTRODUCTION
The supply of good quality essential drugs was recommended in the Alma-Ata declaration of 1978 as one of the prerequisites for the delivery of health care. When the concept of Essential Drugs List (EDL) was introduced by World Health Organization (WHO) some governments embraced it, Kenya included. They developed EDLs on which they based their procurements in terms of maximum quantity at minimum cost. The drugs procured from both local and international suppliers are assumed to be of good quality. This however, seems to have resulted in “cheap” drugs which in some occasions are of questionable quality (Kibwage 1998).

The WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce has not achieved the desired results. The reasons for this are many and varied. They nevertheless revolve around the tenets of WHO procurements which usually assume that an adopting or implementing country has the will and implementing mechanisms to achieve the objectives. Nevertheless, a quality drug is the most critical armamentarium in the treatment or management of some disease states. Drug registration constitutes the first line activity in ensuring that a product on the market is efficacious, safe and of good quality. (Editorial Afr J Pharm 2003). Thus most countries require that drugs must be evaluated and registered before they are allowed to be freely sold within their jurisdiction.(Thoithi 2003). In some countries drug registration exercises are complemented by a Drug Quality Control Laboratory which monitors quality of products on the market. In some cases the laboratory carries out an analysis in order to finalize an application for registration of a drug.

A new product so termed “the innovator brand” sets the benchmark on quality of the drug molecule. The pharmaceutical development of a dosage form and use of the same in clinical trials will establish quality parameters such as, quantity of active ingredient, allowable levels of degradation products and related substances and dissolution disintegration tests amongst others. Other quality indicating parameters must conform to compendia requirements for the type of dosage form.(Renington 1990). Any generic formulations that may be developed later on must of necessity be equivalent to the innovator product in terms of quality. The quality of generics is an area that requires critical scrutiny during the vetting of documents. While the drug molecule is well known in terms of safety and efficacy, pharmaceutical
formulations cannot be the same. In Kenya, samples of products are sent to the National Quality Control Laboratory (NQCL) for evaluation of quality before registration (Dehouk 2003).

Quality Assurance (QA) in the pharmacy context refers to the total sum of all those processes that are necessary to ensure the drug product is of good quality, effective and safe up to the point it is administered to the patient within its stated shelf life. It involves several aspects which broadly fall into four categories. The first aspect of QA involves registration of the drug product prior to marketing in the recipient country. A dossier containing all relevant information on the product is submitted and evaluated by a committee of experts representing different specialties. Information sought includes evidence of quality, safety and efficacy. QA measures must meet internationally accepted standards as defined in such compendia as European Pharmacopoeia, British Pharmacopoeia, and US Pharmacopoeia. Stability data to support recommended shelf life must be submitted. Other information includes evidence of registration in country of origin and other countries where quality assurance measures are enforced.

The second aspect of QA is evidence of Good Manufacturing Practice (GMP), which must focus on the standard of raw material, the manufacturing facility, the in-house production and control measures, packaging, storage, quality control of finished product, qualifications and competence of personnel. In earlier years emphasis had been on analysis of finished product, but later in the 1970's emphasis shifted to GMP (Omura 1986).

The third aspect of QA is the control of the finished product. Although the manufacturer of a drug product is expected to carry out analysis of the product as part of GMP, it is necessary for such results to be validated by an independent and reputable laboratory. Tests include confirmation of label specifications, dissolution rates, and limit tests for contaminants and degradation products. For a generic product, the innovator product serves as point of reference. For antibiotics, chemical assay serves a limited purpose and the antimicrobial assay is preferable. For generic drugs, bioequivalence studies are considered mandatory (Koech 1979).

The fourth aspect of QA is pharmacosurveillance (post marketing surveillance) of drug products. Despite all the precautionally measures taken to ensure safe and effective product, there are some unpredictable variables which could impact negatively as the product moves along the supply line from the manufacturer, wholesaler, retailer/hospital, and eventually the patient (Editorial Afr J.pharm 2003).

The data generated by previous researchers goes to emphasize that there are both good quality and poor quality products in Kenya (Chitneni et.al 2004). The magnitude of poor quality products remains to be determined. This would require well thought out market surveillance programmes by NQCL, Drug Analysis and Research Unit (DARU) and any other similar laboratories. Such programmes should be funded by the Pharmacy and Poisons Board as one of their objectives in ensuring quality drugs in the Kenyan market.

**Situation in Kenya**

In Kenya, the National Quality Control Laboratory (NQCL) is the quality control arm of the Pharmacy and Poisons Board established under the Pharmacy and Poisons Act, Cap 244. The objective of the NQCL is to ensure that the quality of drugs available on the Kenyan market are safe, efficacious and of high quality. This is achieved by appropriate testing of drugs before the Pharmacy and Poisons Board registers them (O'Neil et.al 2001).

Over the past years, Kenya has been treated to press reports about poor quality pharmaceuticals in the market and problems with the same in public institutions (Leal 2001). This therefore, raises concern about the quality of generic drugs in the market. Defects in the regulatory procedures have made it attractive for some traders to introduce substandard generic medicines in the market. The Generic drugs are as safe as their branded counterparts only if the later have passed the quality control and safety tests. However, there still remains a question on the quality of these drugs.

During manufacture of antibiotics, the drug content and physical characteristics are closely monitored to avoid incidences of producing substandard products. (Hilton et.al 1994).

This is done through in-process quality control and quality control of finished products. However, incidences of antibiotics having less drug content than the claimed content are common. The products especially tablets may also have poor disintegration time and hardness. (Omura et.al 1984).

Previous work shows that there are both good quality and poor quality products in Kenya. The magnitude of poor quality products remains to be determined. This would require well thought out market surveillance programmes by NQCL, DARU and any other similar laboratories (Renington 1990). Previous market surveillance studies have been done on many products on the Kenyan market. A previous study on quality of amoxycillin preparations on the Kenyan market indicates that following the evaluation of the content of some 33 amoxycillin capsule formulations, all the failed products were
manufactured locally. (Kamau et al. 2003). In the same study, the evaluation of the amoxicillin content in oral suspensions indicates that the content of amoxicillin in all the products changed within the seven days under the storage conditions. Study done on quality control of antiretroviral drugs analyzed in the Drug Analysis and Research Unit during 2000-2003, indicates that a total of 33 drugs samples were analyzed of which 31 (93.9%) were generic products and only 2 were innovator products (Obuga et al. 2003). This reflects the current government policy to encourage marketing of generic ARVs, which are far much affordable than the brands. The analysis results obtained showed that 30 of the samples complied with the USP specifications while 3 generic products failed the assay test.

Surveys have also been done on quality of sulphadoxine/pyrimethamine tablet products on the Kenyan market (Kibwage et al. 2000). This involved the evaluation of parameters of the tablets that are likely to affect their bioavailability, that is, the content of active ingredients (APIs) and dissolution. In the study 26 batches were analyzed of which the content of APIs for all the examined batches were within the USP limits of the label amount except for one batch which was below the limits. On the dissolution test only 30% of the analyzed samples passed the test. A study done on the quality of ampicillin preparations on the Kenyan market indicate that upon evaluation of the chemical content of 20 ampicillin capsules and 2 tablet products, four capsule products failed to comply with the pharmacopoeal label claim (Kamau et al. 2001). In the same evaluation the content of ampicillin in oral suspensions for five products failed the test. Analysis of co-trimoxazole products on the Kenyan market has also been done whereby in the study there were a total of 9 samples from 7 local products of which 2 failed the content. Of the 9 imported products, 13 samples were analyzed and 4 failed the content specifications. Six samples failed the specifications for content of active ingredients. (Kibwage et al. 1998). An observation on drug quality control in Kenya by the Drug analysis and Research Unit indicates that the failure rate of drugs analyzed in DARU over the period 1996-2000 is higher (23.6%) compared to those analyzed in the same laboratory in the period 1991-1995 (17.5%) (Tirothi 2002). There is therefore need for manufacturers to pay attention to such batch to batch variations that may arise and identify causes of them. The use of poor quality products especially antibiotics can have serious consequences including development of drug resistance and therapeutic failure. The results of these studies support the continuing need for quality certification before and market surveillance after products are released into the market by reputable laboratories as more products enter the Kenyan market. Despite the many studies on drug products on the Kenyan market and that erythromycin is also listed in the Essential Drug List, so far there is no study on erythromycin as to matters of quality. Therefore, this study is directed at ascertaining the quality of some of the erythromycin products on the Kenyan market.

**Erythromycin**

Erythromycin, produced by Saccharopolyspora erythraea (formerly known as Streptomyces erythraeus) is a complex macrolide antibiotic consisting of erythromycin A, a 14 membered lactone ring with a 9-keto group, carrying a neutral and amino sugar (Labenda 1987). It has two glycosidic bonds and a basic dimethylamino group on desosamine. The biosynthesis of erythromycin can be divided into two phases. In the first phase the polyketide synthase (PKS) catalyzes sequential condensation of one unit of propionyl CoA and six units of methylmalonyl CoA to give 6-deoxyerythronolide B, the first enzyme-free intermediate. In the second phase 6-deoxyerythronolide B is elaborated by a series of “tailoring” enzymes which include regiospecific hydroxylases, glycosyl transferases, and methyl transferases. From the biosynthetic point of view most interest is focused on the operations of the PKS in phase 1, but the late steps are essential to produce active antibiotics. Semi-synthetic derivatives of Erythromycin have been directed at producing compounds with increased potency and increased stability in acidic and basic environments. These include roxithromycin, azithromycin, flurithromycin and clarithromycin.

**Erythromycin Indications**

Erythromycin stearate has been used for long in treatment of infections caused by susceptible strains of the designated organisms in many diseases which includes respiratory tract infections especially upper respiratory tract infections of mild to moderate degree caused by Streptococcus pyogenes, Streptococcus pneumoniae, or Haemophilus and lower respiratory tract infections of mild to moderate severity caused by Streptococcus pneumoniae or Streptococcus pyogenes. It is also used in respiratory tract infections due to Mycoplasma pneumoniae and skin and skin structure infections of mild to moderate severity caused by Streptococcus pyogenes or Staphylococcus aureus.

In addition, it is indicated in pertussis (whooping cough) caused by Bordetella pertussis. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals rendering them noninfectious. In infections due to Corynebacterium diptheriae, it is used as an adjunct to antitoxin to prevent establishment of carriers and to eradicate the organism in carriers. Erythromycin is also used in intestinal amebiasis caused by Entamoeba histolytica.
acute pelvic inflammatory disease caused by Neisseria gonorrhoeae and treatment of infections caused by Chlamydia trachomatis. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of nongonococcal urethritis caused by Ureaplasma urealyticum. Moreover, it is indicated in primary syphilis caused by Treponema pallidum. Erythromycin (oral forms only) is an alternative choice of treatment for primary syphilis in patients allergic to the penicillins. It is also used in Legionnaires’ disease caused by Legionella pneumophila and prophylaxis in prevention of initial and recurrent attacks of rheumatic fever. Erythromycin has been used for treatment of several infection diseases and in patients allergic to the penicillins (Ray et al. 2004).

Microbiological Assay
This is a technique whereby the potency or the concentration of a chemical substance may be determined by its effect on the growth of a microorganism either by promoting the growth or by inhibiting the growth. The potency of a sample of an antibiotic is determined by comparing the dose that inhibits the growth of a suitable susceptible microorganism with the dose of the standard preparation of that antibiotic that produces similar inhibition. Biological methods directly detect biological activity and measure potencies of antibiotics hence are preferred in the analyses of antibiotics. In case of related substances which show activity, this method cannot be used. It is time consuming and labor intensive.

Disintegration Time Test
Disintegration is defined as that state in which no residue of the tablets and capsules, except fragments of undissolved coating, remains in the test solution. The method provides a rough estimate of the time limit (30 minutes) required for all uncoated tablets and capsules and all soluble, dispersible, effervescent, and film-coated tablets, that is, all quick release formulations of a drug dosage form to disintegrate in water at 37±2°C. If a drug product does not pass this test, there is a major defect in its quality because it will not dissolve, absorb and become bioavailable. The product can be rejected at this stage with no further investigation (Renington 1990).

Friability Test
This is one of the criteria for testing mechanical strength of tablets. During the process of coating and transportation, the tablet will lose some weight. To measure the weight loss the samples are counted and weighed. Thereafter, the friability test is performed following the individual monographs of the relevant pharmacopoiea. When finished, the samples have to be de-dusted and weighed again. The difference between the weight before and after the test is determined as friability, which should not usually exceed 1% (British pharm 2005).

LIMITATIONS OF THE STUDY
Tablet Hardness Test was not done because there were no B.P. Specifications for film coated erythromycin tablets. Again, due to financial constraints the study could not cover other drugs in the market.

MATERIALS AND METHODS
The study was carried out in Meru Town of Meru County, Kenya. This was to determine the quality of generic erythromycin tablets sold in the chemist shops selling human medicine. The study was guided by analytical study design, through, performing microbiological assay, disintegration test and friability test of tablets.

After listing the chemists (50), erythromycin tablets (20) were purchased from randomly sampled chemists (20) and taken to the laboratory for analysis, (total tablets 400).
To ascertain the quality of generic Erythromycin tablets collected, the following tests were carried out: disintegration time test, friability test and microbiological assay method.

### Table I: Drugs collected for the study

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Manufacturer</th>
<th>Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythrocin 500 mg Tablets (original)</td>
<td>Abbott Pharmaceuticals</td>
<td>Surgipharm Ltd</td>
</tr>
<tr>
<td>Erycin 500 mg Tablets</td>
<td>Flamingo Pharmaceuticals</td>
<td>Harley's Ltd</td>
</tr>
<tr>
<td>Erocos 500 mg Tablets</td>
<td>Cosmos Ltd</td>
<td>Galaxy Pharmaceuticals Ltd</td>
</tr>
<tr>
<td>Erocos 250 mg Tablets</td>
<td>Cosmos Ltd</td>
<td>Galaxy Pharmaceuticals Ltd</td>
</tr>
<tr>
<td>Rhythro 500 mg Tablets</td>
<td>Medrich Pharmaceuticals</td>
<td>Surgipharm Ltd</td>
</tr>
<tr>
<td>Elocin 250 mg Tablets</td>
<td>Elys Pharmaceuticals</td>
<td>Elys Chemical Industries Ltd</td>
</tr>
<tr>
<td>Throcin 500 mg Tablets</td>
<td>Zest Pharma India</td>
<td>Sal Healthcare Ltd</td>
</tr>
<tr>
<td>Erymycin 250 mg Tablets</td>
<td>Remedica</td>
<td>Twokay Chemicals Ltd</td>
</tr>
</tbody>
</table>

**EQUIPMENT AND APPARATUS**

Sartorius CP225D Balance (Elister 2000 Ltd., Namur, Belgium) used for weighing accurately the samples. Friabilator model PTF1 (Pharmatest GmbH, Germany) used for carrying out the friability test. Disintegration tester PTZ1 (Pharmatest GmbH, Hainburg, Germany) used for carrying out the disintegration time test. Schleuniger-2E, tablet hardness tester used for carrying out the tablet hardness test. BRANSON 2200 stirrer (analis, Namur, Belgium) used for ensuring complete dissolution of solutes. MEMMERT incubator Range BE (analis, Namur, Belgium) used for incubating the microorganism cultures. AC600 Series vertical laminar flow workstation (Vermeulen 1,j, Germany) used for carrying out the microbiological procedures. Mettler Toledo PB3002 Data Range weighing balance (Switzerland) used for weighing reagents and media. Dixons ST19 Aluminium portable autoclave (UK) used for sterilizing the media. MEMMERT Universal Oven and Sterilizer Model U (Analis sa, Belgium) used for drying and sterilizing glassware. LMS Laboratory refrigerator used for storing culture plates and microorganisms. An electronic digital caliper used for measuring the zone of inhibition.

**RESULTS**

### Disintegration Time Test

One tablet or capsule was placed into a 100-150 mL wide neck bottle containing 100 mL water at close to 37± 2°C. The liquid was then stirred by swirling the bottle periodically. The time (in minutes) when disintegration is complete was read and recorded. The test was repeated on five additional tablets.

The batch passes disintegration time test if all six tablets disintegrate within 30 minutes. Should one tablet fail to disintegrate, the entire test cycle was to be repeated. The batch fails disintegration test if one of the additional tablets fail again in the second run.

**Table 11: Disintegration Time Test**

<table>
<thead>
<tr>
<th>Tablet</th>
<th>Time in Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13:24</td>
</tr>
<tr>
<td>2</td>
<td>11:10</td>
</tr>
<tr>
<td>3</td>
<td>7:48</td>
</tr>
<tr>
<td>4</td>
<td>12:58</td>
</tr>
<tr>
<td>5</td>
<td>14:02</td>
</tr>
<tr>
<td>6</td>
<td>12:36</td>
</tr>
</tbody>
</table>

**Friability test**

The test was carried out as per the B.P 2007 VOLUME 1V APPENDIX XVII G method using a friabilator. The results obtained are shown in table 2.3

**Table 111: Friability Test**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Weight of 20 tablets (g)</td>
<td>10.8905</td>
<td>19.9372</td>
<td>15.7941</td>
<td>15.7175</td>
<td>18.3514</td>
</tr>
<tr>
<td>Weight of 20 tablets after 100 turns (g)</td>
<td>10.8821</td>
<td>19.9321</td>
<td>15.7921</td>
<td>15.7116</td>
<td>18.3492</td>
</tr>
<tr>
<td>Weight lost (g)</td>
<td>0.0084</td>
<td>0.0051</td>
<td>0.002</td>
<td>0.0059</td>
<td>0.0022</td>
</tr>
<tr>
<td>Percentage Friability</td>
<td>0.07</td>
<td>0.03</td>
<td>0.013</td>
<td>0.04</td>
<td>0.012</td>
</tr>
</tbody>
</table>

Speed: 25 U/min for 4 mins
Microbiological assay
Diffusion Assay Method A BP (2005)
Tryptone Soya Agar (4.0g) was suspended in 100.0 mL of distilled water and brought to boil to dissolve completely. This was then sterilized by autoclave at 121°C for 15 minutes. A solution of phosphate buffer of pH 8.0 was prepared by mixing 50 mL of 0.2M potassium dihydrogen orthophosphate with 46.80 mL of 0.2M NaOH VS and diluted to 200.0 mL with water. A concentration of 30 mg/50 mL of the standard in distilled methanol was prepared by weighing 31.05 mg of erythromycin A base 96.6% and dissolving in methanol in a 50.0 mL volumetric flask.

The test sample was prepared by weighing and powdering 20 tablets. A quantity of the powder containing the equivalent of 30 mg of Erythromycin was dissolved as completely as possible in sufficient methanol to produce 50.0 mL and the biological assay of antibiotics for erythromycin carried out. Dilution of the sample and standard solutions was carried out as follows. From the original solution, 5.0 mL of the solution was transferred to a 25.0 mL volumetric flask and made up to the mark with the phosphate buffer. 10.0 mL of this solution was further diluted to 25.0 mL with the phosphate buffer. Finally, 10.0 mL of this solution was transferred to a third 25.0 mL volumetric flask and made up to the mark with the phosphate buffer. The volumetric flasks were labeled accordingly.

Petri dishes were filled to a depth of 3 to 4 mm with a tryptone soy agar medium that has previously been inoculated with 1% w/v of a suitable inoculum of Bacillus pumilis. When the inoculum consisted of a suspension of vegetative organisms, the temperature of the molten agar medium was not exceed 48°C to 50°C when it was inoculated was kept at a temperature of 37°C. The dishes were specially selected with flat bottoms and placed on a level surface so as to ensure the layer of the medium will be of a uniform thickness. The inoculated plates were allowed to dry for 30 minutes at room temperature before use.

Wells 5 to 8 mm in diameter were bored in the medium with a sterile borer. Solutions of the standard preparation of known concentration and solutions of the substance being examined were prepared in a sterile phosphate buffer of a suitable pH value. The solutions were then introduced to the wells by means of a pipette. Three different doses of the standard preparation and of the sample being examined having the same presumed activity as the solutions of the standard were used in order to be able to assess the validity of the assay. The plates were maintained at room temperature for 2 hours, during which time diffusion of the antibiotic into the medium occurs then incubated at suitable 37°C for approximately 18 hours. The diameters of the zones of inhibition produced by various concentrations of the Standard Preparation and the substance being examined were then measured using the zone reader (British pharm 2005). The potency was then calculated according to the following formula.

Formula 1:
\[ E = \frac{1}{4} (R3 + T3 - R1 - T1) \]
\[ f = \frac{1}{4} (T3 + T2 + T1 - R3 + R2 + R1) \]
\[ b = E + f \]
\[ m = \frac{b}{f} \]
\[ \text{Antilog} m \]
\[ \% \text{LC} = \frac{\text{Weight of Standard}}{\text{Antilog} m} \times \text{Purity} \times 100 \]
Sample (equivalent of 1 tablet)

Where R3, R2 and R1 are zone diameters corresponding to the most concentrated to the least concentrated of the standard samples respectively and T3, T2 and T1 are zone diameters corresponding to the most concentrated to the least concentrated of the test samples respectively.

Table 1V: Potency of the products analyzed (%Label Claim)

<table>
<thead>
<tr>
<th>Product</th>
<th>% label claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rythro 500 BN: RE6001</td>
<td>98.6%</td>
</tr>
<tr>
<td>Erococ 250 BN: 062202</td>
<td>106.3%</td>
</tr>
<tr>
<td>Erococ 500 BN: 062117</td>
<td>101.7%</td>
</tr>
<tr>
<td>Elocin BN: 6F250</td>
<td>96.9%</td>
</tr>
<tr>
<td>Elocin BN: 7C55</td>
<td>109.1%</td>
</tr>
</tbody>
</table>

DISCUSSION
According to the B.P. (2005) specifications for uncoated tablets the tablets disintegrate within 15 minutes unless otherwise justified and authorized. If the preparation fails to comply because of adherence of the tabs to the discs, a repeat of the test on a further 6 tablets omitting the disc is required. The preparation being examined complies with the test if all 6 tablets have disintegrated. Rythro 500 (BN RE6001) is an uncoated erythromycin tablets. The disintegration time test for the six tablets was about one minute. All the tablets disintegrated within this time. The tablets therefore, comply with the B.P disintegration test for tablets and capsules. In case of coated tablets, unless otherwise justified and authorized, film coated tablets disintegrate within 30 minutes and other coated tablets disintegrate within 60 minutes. The preparation being examined complies with the test if all 6 tablets have disintegrated in the medium. Erococ 500 (BN 062202), Erococ 500 (BN 062117), Elocin (BN 6F250) and Elocin (BN 7C55) were film coated erythromycin tablets. The four batches comply with the B.P. disintegration test for tablets and capsules.

In reference to the B.P. (2007) specifications, generally the friability test is run once. If obviously cracked, cleaved or broken tablets are present in the tablet sample after tumbling, the sample fails the test.
A maximum loss of mass (obtained from a single test or from the mean of 3 tests) not greater than 1% is considered acceptable for most products. All the samples passed the friability test as per the B.P. (2007) specifications.

The B.P. (2005) limits of biological assay for erythromycin specifies that the precision of the assay is such that the fiducial limit of error is not less than 95% and not more than 105% of the estimated potency. Rythro 500 (BN RE6001), Erococ 500 (BN 062117), and Elocin (BN 6F250) comply with the B.P specifications for the fiducial limit of error. However, two products, Erococ 250 (BN 062202) and Elocin (BN 7C55), failed the test because they had a higher value than the stated percentage label claim. These did not comply with the B.P specifications for the fiducial limit of error of not less than 95% and not more than 105% of the estimated potency. Products with higher quantity than the specified amount of the drug can result in increased levels of toxic effects of the drug. On the other hand, low quantity of the drug will lead to pharmacological ineffectiveness and promote the development of drug resistant parasites.

There are many generic erythromycin tablets in the Kenyan Market, the quality of which remains uncertain. There is therefore, the need for critical control of the quality of generic erythromycin tablets in the Kenyan Market. The quality specification for the active and non-active ingredients should be of interest to manufacturers and the drug regulatory authorities. The performance of the dosage form during a claimed shelf life in comparison to the innovator product should be routinely assessed. This will help in the prevention of development of erythromycin resistance.

The results obtained show that two products of the tablets analyzed do not comply with the B.P specifications for the estimated potency

CONCLUSION
The objective of the study was to analyse the sampled erythromycin tablets in order to determine their quality. The samples analyzed passed disintegration time test and friability test except microbiological assay. This may be due to faulty quality assurance and control during the process of manufacture or inadequate storage conditions in the supply chain.

RECOMMENDATIONS
The following recommendations were drawn from the findings of the study.

1. There is need for sustained market surveillance of erythromycin drugs to ensure quality standards are maintained.
2. That further research should be done in order to establish the quality of other drugs in the market.

REFERENCES


