An Investigation into the Management of Pharmaceutical Wastewater in Kenya

Ms. Anne W. Njuguna, Prof. Alfred O. Mayabi, Eng. Wangai Ndirangu

Abstract—The pharmaceutical industry manufactures biological products and medicinal drugs, which may pass into the environment as the parent compound or as active metabolites, referred to as Pharmaceutically Active Compounds (PhACs). PhACs can enter into the environment through numerous scattered points, but the main sources of contamination are pharmaceutical production plants and hospital effluents. The presence of PhACs in the environment is a growing concern because of their toxicity, bio-accumulating tendency, and threat to the environment. Pharmaceutical effluent also contains a substantial amount of suspended solids and Chemical Oxygen Demand (COD), which need to be reduced to acceptable levels before disposal. The pharmaceutical industry in Kenya has been growing over the years and the country is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50 per cent of the region's market. This has resulted in an increase in the volume and variety of the wastewater produced and consequently the negative effects in the eco-system and human life. Currently, there is limited literature on the management of pharmaceutical effluent in Kenya. Therefore, the aim of this study is to investigate and evaluate the generation and characteristics of pharmaceutical wastewater in Kenya and the pre-treatment methods employed by different factories, to ensure proper management of the effluent so as to minimize contamination and ecosystem disruptions. Data was collected through observation of the manufacturing processes and wastewater treatment facilities in sampled factories as well as interviews and questionnaires given to technical personnel in charge of effluent treatment plants in the factories. In addition to this, laboratory tests were carried out on sampled wastewater from the factories.

***Keywords*—**Industrial wastewater, Pharmaceutical effluent, Pharmaceutically active compounds, Wastewater treatment.

I. Introduction

Pharmaceutical companies in Kenya include local manufacturing companies, and large multi-national corporations, subsidiaries or joint ventures. Most are located within Nairobi and its environs. The products under this sector include medical equipment and medicinal drugs in form of tablets, syrups, capsules, and injectables among others. The country exports its pharmaceutical products to Tanzania, Uganda, DRC, Rwanda, Burundi, the Comoros, Ethiopia and Malawi among other destinations. The number of companies engaged in manufacturing and distribution of pharmaceutical products in Kenya continues to expand, driven by the government's effort to promote local and foreign investment in the sector[1]. The bulk of locally manufactured preparations are non-sterile, over- the-counter products, such as antibiotics, analgesics, or bronchial spasm relaxants, and there is little variation of the type of products from one company to another[1], [2]. Table 1 shows some of the leading pharmaceutical manufacturing companies in Kenya. These companies fall under the formulation, drug mixing and preparation plant category of pharmaceutical industries. They mainly use raw materials such as sugar, corn syrup, lactose, gelatin, calcium, talc, alcohol, glycerin and aspirin which result in substantial amounts of organic pollutants[3].

TABLE I
LEADING PHARMACEUTICAL MANUFACTURING COMPANIES IN KENYA

Company name	Location
Alpha Medical Manufacturers	Nairobi
Aventis Pasteur SA East Africa	Nairobi
Bayer East Africa Limited	Nairobi
Beta Healthcare (Shelys Pharmaceuticals)	Nairobi
Cosmos Limited	Nairobi
Dawa Pharmaceuticals Limited	Nairobi
Didy Pharmaceutical	Nairobi
Diversey Lever	Nairobi
Eli-Lilly (Suisse) SA	Nairobi
Elys Chemical Industries Ltd	Nairobi
Glaxo SmithKline	Nairobi
High Chem East Africa Ltd	Nairobi
Ivee Aqua EPZ Limited	Athi River
Mac's Pharmaceutical Ltd	Nairobi
Manhar Brothers (Kenya) Ltd	Nairobi
Novartis Rhone Poulenic Ltd	Nairobi
Novelty Manufacturers Ltd	Nairobi
Pfizer Corp (Agency)	Nairobi
Pharmaceutical Manufacturing Co (K) Ltd	Nairobi
Pharmaceutical Products Limited	Nairobi
Phillips Pharmaceuticals Limited	Nairobi
Regal Pharmaceutical Ltd	Nairobi
Universal Pharmaceutical Limited	Nairobi

The steady growth of the pharmaceutical industry in Kenya has resulted in an increase in industrial discharges which poses a problem in waste management. There is increasing concern

A. W. Njuguna, Department of Civil, Construction and Environmental Engineering, JKUAT (Phone: +254723493940; E-mail: annenjuguna07@gmail.com).
A. O. Mayabi, Department of Civil, Construction and Environmental Engineering, JKUAT (E-mail: drmayabi@eng. jkuat.ac.ke).
W. Ndirangu, Department of Civil Construction and Environmental Engineering, JKUAT (E-mail: wangai@beassociates.co.ke).

that Pharmaceutically Active Compounds(PhACs)in the environment, even in trace amounts will progressively have a negative impact on aquatic organisms and humans, especially when different pathogenic bacteria develop tolerance to anti-microbial drugs[4]. A wide variety of these compounds have been detected in different water samples from rivers, groundwater and drinking water sources and studies have shown that these pollutants are toxic even at low concentrations [5]–[7].Convectional biological WWTPs are designed to remove carbon, nitrogen and phosphorous, however, PhACs often go through the normal treatment plant unaltered. A study conducted on a pharmaceutical plant in Kenya that used chemical coagulation followed by activated sludge process showed that the treated effluent quality was not always up to the required standard mainly because PhACs were toxic to the bacteria in the activated sludge. In addition to this, there was also a high residual concentration of the pharmaceuticals in the treated effluent [8]. Another study revealed that Kenyan rivers are heavily contaminated by PhACs, with antibiotics being the most common class of pharmaceuticals detected[5].

In addition to the problems associated with PhACs, another factor to consider in the pre-treatment of pharmaceutical effluent is the substantial amounts of organic pollutants trapped in suspended solids. High amounts of organic pollutants in suspended wastewater solids result in undesirable environmental effects due to microbial growth, deposition of sludge blanket, possible toxicity and turbidity in receiving bodies [9], [10]. Usually, pharmaceutical wastewaters have a high Chemical Oxygen Demand (COD) concentration and relatively low Biochemical Oxygen Demand (BOD), meaning that the wastewater has a poor biodegradability. Reduction of these organic pollutants to permissible concentrations is necessary for the protection of ground and surface water, and human and environmental safety [11]. Thus there is need for proper management of pharmaceutical effluent to minimize contamination and ecosystem disruptions. Therefore, the objectives of this study was to investigate the generation of pharmaceutical wastewater in Kenya, to characterize the specific qualities of the wastewater and to find out the pre-treatment methods employed by different factories.

II. Materials and Methods

An investigation was carried out to determine the types of pharmaceutical factories most common in the country, the amount of wastewater they produce daily, the pretreatment processes they carry out and the challenges they face in handling the effluent. A desk study was done as well as visits to several factories, which were selected through simple random sampling. Information was collected through observation of the manufacturing processes and treatment facilities in the factories as well as interviews and questionnaires given to technical personnel in charge of effluent treatment plants in the factories.

For this study, raw wastewater was obtained from three pharmaceutical plants in Kenya, herein referred to as 'Factory A', 'Factory B' and 'Factory C' in order to protect their confidentiality. The selection of these factories was based on those which were cooperative in providing information and giving access to their facilities for data collection. The wastewater from each factory was collected using composite samples which were made up of three grab samples that were collected at an interval of two days so as to account for variations in production processes in the factories within a week. The first set of samples were collected at the end of the production process and before any treatment procedures were carried out on the wastewater. Analysis results of these samples were used in the characterization of pharmaceutical wastewater. A second set of samples were collected at the end of wastewater treatment processes in the factories and these were used to determine the efficiency of the treatment systems. The samples were collected in five liter plastic containers, which had been previously prepared by scrubbing with a brush and laboratory detergent, then rinsed three times with tap water. This was followed by rinsing with distilled water, after which they were allowed to air dry.

During sample collection, nitrile gloves and lab coats were used as protective gear. Following the collection of the samples, the containers were sealed and labeled with an identifying number, the date, time and the location of collection. They were placed in a sample cooler with ice before being transported to the laboratory where analysis was carried out. In the laboratory, the samples were refrigerated at a temperature of between 4 and 8 degrees Celsius. During preparation for analysis, the samples were thoroughly mixed so as to produce a homogeneous sample. Analysis was carried out for pH, Total Suspended Solids (TSS), turbidity, COD, Total Organic Carbon (TOC), BOD, and PhACs.

The pH of the sample water was measured with a WTW pH-meter which was calibrated with two buffer solutions (pH 7.00 and pH 4.00) before use. Measurements were taken by placing the electrode of the pH meter into the sample and allowing the readings to stabilize. The electrode of the pH meter was carefully rinsed with deionized water whenever it was taken from one sample to another, so as to avoid cross-contamination.

To measure the TSS of the effluent, a well-mixed sample was filtered through a weighed standard glass-fiber filter and the residue retained on the filter was dried to a constant weight at 103°C to 105°C. The increase in weight of the filter represented the total suspended solids and was calculated using equation 1.

$$mg/TSS/L = \frac{(A-B)\times 1000}{Samplevolume \quad (ml)} \tag{1}$$

Where;

A - Weight of filter + dried residue, mg

B - Weight of filter, mg.

Turbidity was measured using a TR-3 turbidi-meter which produces readings on a liquid crystal display in Nephelometric Turbidity Units (NTU). The turbidity meter was calibrated with 20 NTU and 100 NTU standard solutions, after which the samples were put in vials and placed in the meter for analysis.

Determination of COD was done using the closed reflux titrimetric method. 10.0 ml of the samples, together with one blank were put in well cleaned digestion tubes. Following this, 6.0 ml of 0.0167 molar potassium dichromate solution was added into the digestion tubes. 14.0 ml of sulfuric acid reagent was then carefully run down the walls of the tube after which the tubes were tightly capped and slowly inverted several times for complete mixing so as to prevent local heating of the vessel bottom which could result in an explosive reaction. The digestion tubes were then placed in a block digester and heated at 105^{o}C for 2 hours. They were allowed to cool to room temperature and placed in a tube rack. Thereafter, the contents were transferred into a conical flask and 2 drops of ferroin indicator were added and this was titrated with 0.10 molar ferrous ammonium sulfate (FAS) to a sharp color change from blue-green to reddish brown. The blank was likewise titrated. The COD value was calculated using equation 2.

$$COD\ (mg\ O_2/l) = \frac{(A-B)\times M\ \times 8000}{Mlsample} \quad (2)$$

Where;

A – ml of FAS used for blank

B – ml of FAS used for sample

M – Molarity of FAS

For TOC analysis, the samples were put in TOC vials which were then placed in a Shimadzu TOC-5000 carbon analyzer. Total carbon (TC) was analyzed by injecting a sample into the combustion tube (+680 °C) filled with oxidation catalyst. Synthetic air was used as a carrier gas. The carbon compounds were decomposed to carbon dioxide gas, which flowed with the carrier gas to infrared gas analyzer where the carbon dioxide was detected. In the inorganic carbon (IC) analysis the sample was injected into an IC vessel where it was acidified. IC component of the sample was decomposed to carbon dioxide and detected by infrared gas analyzer. Total organic carbon (TOC) was obtained by subtracting inorganic carbon (IC) from the analyzed total carbon.

BOD measurement was carried out in the laboratory by diluting different volumes of the wastewater with aerated distilled water in which BOD nutrients (phosphate buffer, magnesium sulfate solution, calcium chloride solution and ferric chloride solution) had been added. The samples were seeded using sludge obtained from a biological treatment plant. In the analysis of BOD, Dissolved Oxygen (DO) of each of the samples was measured before they were transferred into BOD bottles and incubated at 20^{o}C for 5 days. The DO was then measured after the 5 days incubation. The sample BOD was calculated using equation 3.

$$BOD_5(mg/l) = \frac{(D_0-D_5)-(B_0-B_5)f}{P} \quad (3)$$

Where;

D_0 - Dissolved oxygen of the diluted sample immediately after preparation (mg/l)

D_5 - Dissolved oxygen of the diluted sample 5 days after incubation at 20 ^{o}C (mg/l)

B_0 - Dissolved Oxygen of diluted seed sample after preparation (mg/l)

B_5-Dissolved oxygen of diluted seed sample 5 days after incubation at 20 ^{o}C (mg/l)

f – Ratio of percentage seed in diluted sample to percentage seed in seed control

P- Decimal volumetric fraction of sample used

The concentration of PhACs present in the samples was determined using High Performance Liquid Chromatography (HPLC). This method is convenient because it is capable of detecting several compounds at the same time. The equipment used was a Hewlett Packard 1100 –series HPLC.The HPLC system was calibrated for eight pharmaceuticals which are produced by the companies and were expected to be in the wastewater, namely; ciprofloxacin, clotrimazole, diclofenac, sulfamethoxazole, paracetamol, ibuprofen, trimethoprim and metronidazole. This helped to determine the retention time for each of pharmaceutical compounds. For the calibration, 0.1 g of the pure form of each of the pharmaceuticals was dissolved in 100 ml mixture of acetone and distilled water to form a solution with a concentration of 1 mg/ml. from this stock solution, six calibration solutions were prepared in vials. During the HPLC analysis, distilled water was used as blanks. In HPLC, a small amount of sample (10 – 20 µl) is injected to the liquid phase (mobile phase or eluent) using injector. Liquid phase travels evenly in narrow capillaries with the help of pump into the column. The column is packed with stationary phase which consists of small particles. These particles divide the sample into its components which stays in the particles for different time. At each turn, components come out from the column and into the detector which signals a peak into the chromatogram. The samples were filtered through a 0.20 µm filter to the HPLC vials before the analysis

III. RESULTS AND DISCUSSION

A. Wastewater Generation

From the investigations carried out, it was found that pharmaceutical plants in Kenya have little variation in the range of products and formulations. Most of the leading firms all fall under the formulation, drug mixing and preparation plant category that are involved in compounding and packaging medicines, repacking formulated drugs and processing bulk drugs into doses using predominantly imported active ingredients and excipients. These factories are mainly involved in the production of syrups, suspensions and tablets. However, it was noted that the large multinational corporations in Kenya are mainly involved in distribution of pharmaceutical products which are manufactured elsewhere.

The companies involved in production release an average of 2000- 6000 litres of process wastewater per day, mainly from washing of drug formulation and mixing equipment. The

production of creams, suspensions and syrups contributes to about 43% of the wastewater while the processes of granulation and coating of medicinal products contributes about 28% each. All the sampled factories carried out pre-treatment of the wastewater before disposing it or taking it for biological treatment either on site or in the public wastewater treatment plants.

B. Characterization of pharmaceutical effluent

The characteristics of the raw wastewater, which was sampled at the end of the production process from three factories, were determined from analysis and the range of values for the measured parameters are shown in Table II.

TABLE II
CHARACTERISTICS OF PHARMACEUTICAL INDUSTRY WASTEWATER

Measured parameter	Range value
pH	6.18 - 7.08
TSS (mg/l)	74.33 – 210.37
Turbidity (NTU)	63 - 127
COD (mg/l)	195.63 – 418.70
TOC (mg/l)	99.47 – 117.50
BOD (mg/l)	85.23 – 263.23

The pH of the samples ranged from 6.18- 7.08. This was neither too high nor too low. Extremes of pH in wastewater are generally not acceptable because they result in problems in wastewater treatment systems [10]. TSS and turbidity of the samples wastewater ranged between 74.33- 210.37 mg/l and 63- 127 NTU respectively. COD ranged between 195.63-418.70 mg/l, while the range of TOC was 99.47-117.50 mg/l. The BOD range was between 85.23- 263.23 mg/l.

The variations in the concentration and composition of the samples could be attributed to varying production processes that may have been carried out. The effluent is of low strength compared to those reported by other researchers in different countries[10], [12], [13]. According to a study [12] on low strength pharmaceutical wastewater the COD ranged between 460- 526 mg/l, BOD was between 299-386 mg/l and TSS was between 15-50 mg/l. Reference [13] used pharmaceutical wastewater with a COD range of 300- 2000 mg/l, and TSS of between 32-45 mg/l. The TSS values in the present study were higher compared to those observed in the above mentioned studies, but still fall within the range of low strength pharmaceutical effluent as described by[3], which gave the TSS range as 200-400 mg/l. This variation could be a result of use of different raw materials such as cocoa, talc, calcium or gelatin which are required for some formulations. High strength pharmaceutical effluent can have COD values as high as 7280 mg/l, BOD of 4132 mg/l and TSS of up to 4300 mg/l as reported in [10].

The results from the characterization of the samples was within the expected range because the wastewater was from drug mixing and formulation plants, that use various raw materials to prepare drugs in the final form of syrups, tablets, capsules, creams etc., which produces wastewater with a relatively lower waste load compared to other categories of pharmaceutical industries[1], [3].

Table III shows the eight pharmaceutical compounds used tocalibratethe HPLC,the resultant retention times of these compounds, and the maximum concentrations of the compounds found to be present in the wastewater samples.

TABLE III
RETENTION TIMES AND MAXIMUM CONCENTRATIONS OF PHARMACEUTICAL COMPOUNDS IN SAMPLE WASTEWATER

Pharmaceutical compound	Retention time (minutes)	Maximum concentration (mg/l)
Ciprofloxacin	4.801	14.98
Clotrimazole	0.417	-
Diclofenac	7.519	-
Sulfamethoxazole	5.395	62.83
Paracetamol	1.363	-
Ibuprofen	8.579	26.54
Trimethoprim	4.429	208.3
Metronidazole	7.021	29.92

Retention time is the time taken by a compound to pass through a chromatography column and is calculated as the time from injection of the compound into the column to the time it is detected. HPLC analysis of the sample wastewater showed that it contained ciprofloxacin, sulfamethoxazole, ibuprofen, trimethoprim, and metronidazole. The highest concentration was of trimethoprim which was 208.30 mg/l. This compound is a synthetic antibiotic used to treat malaria, respiratory and urinary infections. It is sometimes used in combination with sulfamethoxazole to make it more effective because of the frequent development of its resistance [14]. Sulfamethoxazole, which is an anti-bacterial agent, had the second highest concentration of 62.83 mg/l. Metronidazole and Ibuprofen had a concentration of 29.92 mg/l and 26.54 mg/l respectively. Metronidazole is an antibiotic effective against anaerobic bacteria and some parasites which works by selectively blocking some of the functions within the bacteria cells and the parasites resulting in their death.Ibuprofen is a nonsteroidal anti-inflammatory drug used in the treatment of mild to moderate pain, fever and inflammation [14]. Ciprofloxacin, which is a quinolone antibiotic used to treat a variety of bacterial infections, had the lowest concentration of 14.98 mg/l.

C. Pre-treatment methods

Data collected from the pharmaceutical factories under study showed that each of the factories had its own unique processes of handling effluent. However, despite the variation in processes, all of them carried out coagulation and flocculation as an initial step in the pre-treatment of the wastewater mainly to remove suspended solids and reduce COD. The most commonly used coagulant is aluminium sulfate, ferric sulfate and ferric chloride, mainly because of their availability and relatively low cost.

In Factory A, process water is collected in three equalization tanks each with a capacity of 25,000 liters. From these equalization tanks, the effluent flows into a coagulation tank, where aluminium sulfate is added as a coagulant. In order to enhance the formation and settling of flocs, a polymer

known as Rapid Floc is added during the flocculation process. After the coagulation/ flocculation step, the effluent flows into an aerated balancing tank where it mixes with sanitary wastewater from the factory that has passed through a fine screen. The wastewater then passes through a biological treatment by the activated sludge process. After the treatment, the effluent is allowed to infiltrate into the ground though soak pits. This factory undertakes the biological treatment because it is not connected to a municipal wastewater system due to its location. Through its treatment processes, Factory A achieved removal of TSS, COD, BOD, and PhACs of 79%, 42%, 22%, and 21% respectively. The problems encountered in the treatment of effluent in this factory include high residual TSS, BOD and PhACs. A possible reason for this is that the PhACs present in the effluent could be toxic to bacteria and thus interfere with the activated sludge process. In addition to this, they experienced poor floc formation in the chemical coagulation treatment and when they tried to remedy the situation by introducing the polymer it resulted in high increases in cost because the polymer was imported from South Africa.

In Factory B, wastewater from an equalization tank flows into the coagulation treatment tank where ferric chloride is used for coagulation/ flocculation. In this step, sulfuric acid and sodium hydroxide are used to adjust the pH. After the removal of suspended solids, the effluent is passed through an activated charcoal filter to remove residual color and PhACs, following which the effluent is released into the municipal wastewater system. This treatment system achieved an average percentage removal for TSS, COD, BOD, and PhACs of 84%, 38%, 8%, and 46% respectively. The main problems encountered in effluent treatment in this factory is controlling the high doses of chemical coagulants used and the relatively short service life of the activated charcoal filters, which may at times interfere with the effectiveness of the treatment system.

In Factory C, effluent is collected in four equalization tanks. From there, it flows into the first treatment tank which has a capacity of 24,000 liters and as it does so it passes through a screen bar and blowers which aerate it. In this treatment tank, aluminium sulfate is added as a coagulant as well as a polyelectrolyte that enhances the flocculation process for removal of suspended and colloidal matter. This is followed by ozonation, where an ozonator converts oxygen from an oxygen concentrator into ozone using an electric discharge field. The ozone produced oxidizes organic matter and other pollutants present in the effluent. The effluent goes through two dissolved air floatation tanks where floatable matter is removed. Finally the effluent is passed through an activated carbon filter system where residual organic matter is removed before being released into the municipal sewerage system. A press filter is used for sludge dewatering. This treatment system proved to be the most efficient in parameter removal, achieving an average of 86%, 58%, 17%, and 74% for TSS, COD, BOD, and PhACs respectively. The main challenges encountered in this facility are the high chemical dosages used, high operation and maintenance costs of the equipment and production of large volumes of sludge.

IV. Conclusion

The pharmaceutical manufacturing factories in this study all fall under the formulation and drug mixing category and employ coagulation/ flocculation process to their wastewater as one of the pretreatment steps. Other forms of pretreatment include activated carbon filtration, ozonation, dissolved air floatation and activated sludge treatment.

The pH of the samples collected ranged from 6.18-7.08 while COD, TOC, and BOD ranged between 195.63 – 418.70 mg/l, 99.47 – 117.50 mg/l, and 85.23 – 263.23 mg/l respectively. Based on previous studies on pharmaceutical effluent and available literature, the wastewater produced from Kenyan pharmaceutical factories is of low strength and the variations in its concentration and composition is due to variations in production processes.

An investigation into methods of treating pharmaceutical effluent in Kenya showed that they resulted in an average of 35% to 58% removal of COD and 79% to 86% removal of TSS. There was weak floc formation in most cases which resulted in poor settling. Removal of BOD was low, ranging between 8% and 22%. This however was not a cause for concern because the initial concentration of the BOD was also low in all the cases under study. Apart from the factory that carried out ozonation treatment, removal of pharmaceutical compounds was minimal, thus showing a great need for improvement in this area.

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