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ASSESSMENT OF DRUGS PRODUCTION OPERATIONS IMPACT ON MINERALS AND HEAVY METALS LEVELS OF SOILS AROUND THE FACILITIES

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Pharmaceutical industries, involved in the formulation and production of drugs, have contributed immensely to providing essential medications. However, similar to other industrial operations using conventional methods, chemical spills and environmental pollution are common. This study assessed the impact of pharmaceutical production operations on the levels of Mg, Al, Si, Zn, Fe, and Pb, linked to the raw materials used in production operations, with the exception of Pb. The results revealed that the levels of analyzed minerals and heavy metals followed this magnitude: Fe > Al > Mg> > Zn > Si > Pb. The most and least abundant analytes were Fe (18,348 mg/kg) and Pb (38.32 mg/kg), respectively. The order of contamination, based on the geo-accumulation index, was Zn (0.885) > Pb (0.867) > Fe (-1.75) > Al (-4.77) > Mg (-5.68) > Si (-11.22). Similarly, the contamination factors were in the same order: Zn (2.77) > Pb (2.73) > Fe (0.447) > Al (0.054) > Mg (0.0290) > Si ($6.28 \cdot 10^{-4}$). The geo-accumulation index and contamination factor indicate moderate contamination by Zn and Pb, respectively. In conclusion, the pharmaceutical companies under review have not significantly impacted the environment. Moreover, the moderate organic carbon content (1.45 %), high ECEC (28.50 ± 0.76 cmol/kg), along with the alkaline nature (pH 8.86) of the test sample pharmaceuticals (TSP), may further restrain mineral and heavy metal mobility, such as available phosphorus, zinc, lead, and iron, among others. However, the sandy nature of the soil may ease relative immobilization due to alkaline pH and organic matter.

Keywords: drug compounding operations; soil pollution; potentially toxic metals; contamination assessment.

INTRODUCTION

Pharmaceutical industries have played a significant role in providing healthcare by continuously striving in producing standard drugs as well as providing new cures that aid people live longer and healthier lives. The utilization of pharmaceutical products for the treatment of illnesses dates back thousands of years. In the early days, plants and herbal remedies were predominantly used for treating various diseases and traumas until the introduction of orthodox medicine (Adesina et al., 2018; Afolabi et al., 2020).

Over the years, the manufacturing and utilization of therapeutic products have increased rapidly with the development of drugs. Previous report reveals that approximately 3,000 compounds are used as drugs, with yearly production quantities reaching several tons (Carvalho & Santos, 2016; Grenni et al., 2018).

Documented reports also indicate that industrial operations have an impact on the environment, transforming it from its pre-industrial state (Yerima et al., 2019). Similar to other industrial processes, the production of pharmaceuticals using conventional methods has led to increased chemical pollution in the environment (USEPA, 1995). These issues have garnered increased attention (Yaqub et al., 2012; Barrios-Estrada et al., 2018). Activities in pharmaceutical companies include the preparation of bulk medicinal compounds in various forms such as syrups, tablets, injectable solutions, and capsules, each with the appropriate dosage for direct administration to patients in the correct amount (Yaqub et al., 2012).

Production operations are typically conducted in batches and may involve the use of solvents as a reaction medium, chemical reactions, purifications, centrifugation, drying, and crystallization, among other processes (Metry, 1980). Similar to other industrial operations, pollutants in the form of volatile organic compounds may be emitted, along with pharmaceutical wastewater containing varying concentrations of toxic organic solvents and solid waste. For instance, numerous studies have reported elevated concentrations of heavy metals in effluents from pharmaceutical companies (Olaitan et al., 2013; Shokri et al., 2016), while others have identified the presence of heavy metals even in pharmaceutical products (Geronimo et al., 2013). These heavy metals/metalloids are considered contaminants when present in elevated amounts, capable of causing detrimental effects on the environment and its inhabitants (Singh et al., 2011). Hence, there is a need to determine their status from potential sources and the necessity for continuous monitoring for intervention where necessary.

The aim of this research is to evaluate the impact of pharmaceutical operations on the levels of minerals and heavy metals in soils. Mineral elements were carefully selected based on their connection to the raw materials used in drug production. The results obtained will provide baseline data for minerals and heavy metals around the industries under consideration for future research, as well as insights into the impact of industrial operations on the soil for prompt action.

MATERIALS AND METHODS

Study area and sample collection

The studied industries were all situated in the Jos metropolitan area of Plateau State, Nigeria, with geographical coordinates ranging from latitudes 9°45'00"N to 09°57'00"N and longitudes 8°48'00"E to 8°58'00"E, as depicted in Figures 1 and 2. The study region encompasses parts of both Jos North and Jos South Local Government Areas, accommodating approximately 736,016 people as of the last National Census in 2006, covering a landmass of 249.7 km^2 and an altitude of 1,217 m above sea level (Adzandeh et al., 2015; Umaru et al., 2021).

The pharmaceutical companies under consideration are located at the geographical coordinates 9°44'39.03012"N, 8°53'20.4602"E and 9°54'39.03012"N, 8°53'20.46012"E, respectively, in Jos, Nigeria. Both industries produce similar products such as paracetamol syrup, cough syrup (diphenhydramine), antihistaminic (Chlorpheniramine), Flagyl, sulfur ointment, antacids (containing Mg, Al, Ca, Zn), among others. These industries have been in existence for more than two decades, and waste generated in these facilities is usually managed through incineration.

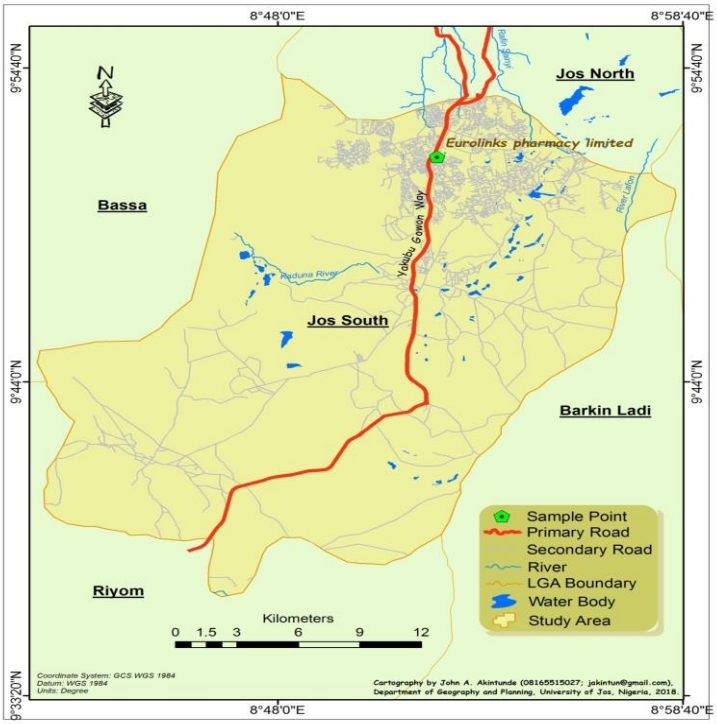

Figure 1. GPS Map of Jos metropolis

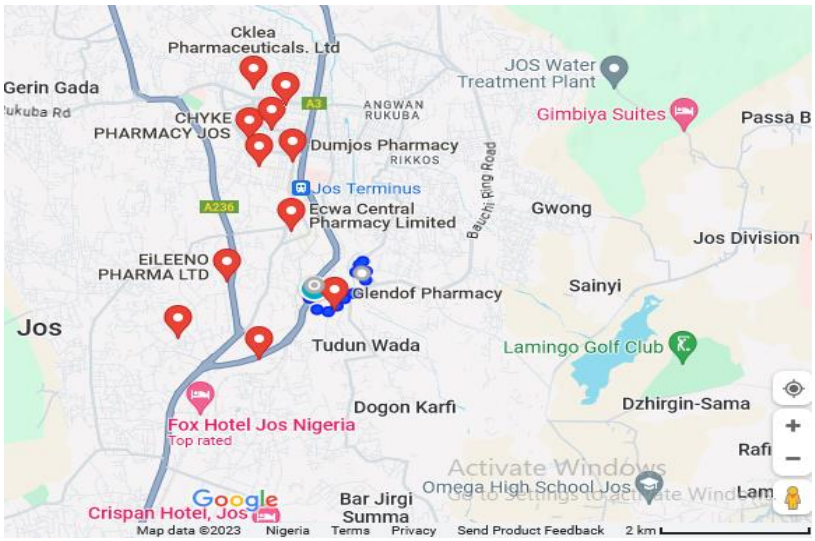

Figure 2. Google Map of Jos

80 soil samples from the topsoil (0 – 15 cm depth), each of approximately equal size, were collected using the grab method and adopting a stratified sampling procedure. 20 samples were collected across approximate areas: north, south, west, and east, corresponding to each pharmaceutical industrial layout under consideration. To account for variability within the study area, the 80 sample components from each facility under consideration were combined to form a composite, creating a representative sample for the study labeled test sample pharmaceuticals (TSP). Another soil sample was collected from a remote area devoid of activities associated with the facility under consideration and used as a control, labeled control sample pharmaceuticals (CSP) (Xue & Cheng, 2001; Yerima et al., 2020).

Sample preparation

The TSP underwent sorting, with removal of gravels and coarse constituents, and was then dried at room temperature. After drying, the TSP was made uniform by grinding and passed through a 2 mm mesh size sieve to eliminate particles larger than 2 mm in diameter. The resulting sample was then utilized for digestion and analysis. The same procedure was applied to the CSP.

Determination of soil physicochemical parameters

The pH of the soil supernatant was measured using a pH meter (JENWAY 2000). For each sample, 1 g of TSP was mixed with 10 mL of distilled water to facilitate the release of hydrogen ions into the mixture. The mixture was allowed to stand for

20 minutes. The same procedure was applied to the CSP (Motsara & Roy, 2008).

Soil organic carbon was analyzed by titrimetric means after the oxidation of carbon with $K_2Cr_2O_7$, following the method described by Walkley and Black (1934) and adopted by Yerima et al. (2020). Nitrogen levels were evaluated using distillation and the titrimetric method described by Kjeldahl. The UV-visible spectrophotometer, set at a wavelength of 660 nm, was used to estimate phosphorus concentration after the development of color upon the addition of the molybdate reagent (Bray & Kurtz, 1945; Yerima et al., 2020).

The textural characteristics of the soils were analyzed using the Hydrometer method (Motsara & Roy, 2008). The Effective Cation Exchange Capacity (ECEC) was calculated using the expression in equation (1). The Exchangeable Acidity (EA) (H^+ and Al_3^+ content) of the soils was quantified by titrimetric analysis, while the exchangeable cations (Na and K content) were quantified using a flame photometer (Sherwood 410). The Ca and Mg content were estimated by titration of soil-ammonium acetate leachate drains (Yerima et al., 2022).

$$\mathrm{ECEC_{sum}}\left(\frac{m_{eq}}{100\ g}\right) = \left(\frac{ppm\ Ca}{200}\right) + \left(\frac{ppm\ Mg}{120}\right) + \left(\frac{ppm\ K}{391}\right) + + \left(\frac{ppm\ Ca}{200}\right) + EA \quad (1)$$

Analysis of minerals and heavy metals levels

To quantify the levels of Mg, Al, Si, Zn, Fe, and Pb in TSP and CSP, 1.0 g of each sample was digested with 10 mL of concentrated HNO_3 using a microwave digestion system set at 95 ± 10 °C for 15 minutes. After cooling, an additional 5 mL of concentrated HNO_3 was added, and the mixture was heated for another 30 minutes and allowed to cool. At this point, 30 % hydrogen peroxide (4 mL) and deionized water (2 mL) were added, and the mixture was heated at 95 ± 10 °C until the digest volume reduced to about 5 mL, then allowed to cool. The digest was filtered and diluted to the 50 mL mark with deionized water. The levels of minerals and heavy metals were quantified using a Micro Plasma-Atomic Emission Spectrophotometer (4210 MP-AES Agilent technologies) (Yerima et al., 2023).

Data Processing and Statistical Analysis

Data obtained from the test and control soil samples were compared using a t-test with the Statistical Package (IBM SPSS Statistics 20) at a 95 % confidence limit. The concentrations of minerals and heavy metals obtained were further subjected to the Index of Geoaccumulation (I_{geo}) and Contamination Factor (C_f) models to assess the pollution impact of the pharmaceutical company on the test soil.

I_{geo}: This aids in evaluating contamination by comparing the current contamination state with the original status before the advent of industrial operations (Muller, 1969; Xue & Cheng, 2001). It measures the degree of contamination in terms of seven enrichment classes based on increasing numerical values of the index. The I_{geo} was calculated using Equation (2).

$$\mathrm{I_{geo}} = \log_2\left[\frac{\mathrm{C_n}}{1.5\mathrm{B_n}}\right] \quad (2)$$

where C_n is the amount of mineral or heavy metal in the soil, and B_n is the geochemical background value (Barbalace, 2007; Sharma et al., 2016). The constant value, 1.5, serves as a background matrix correction factor due to geochemical inconsistency. An I_{geo} value of (0) is defined as Uncontaminated; (0 to ≤ 1) Uncontaminated to moderately contaminated; (1 to ≤ 2) Moderately contaminated; (2 to ≤ 3) Moderately to strongly contaminated; (3 to ≤ 4) Strongly contaminated; (4 to ≤ 5) Strongly to extremely strongly contaminated, while (> 5) indicates Extremely contaminated (Rahman et al., 2012).

The soil contamination assessment carried out in term of C_f was estimated by the expression in Equation (3)

$$\mathrm{C_f} \equiv \frac{[\mathrm{C}]}{[\mathrm{C}]_b} \quad (3)$$

where [C] is the levels of heavy metal or mineral in the investigated area; $[C]_b$ is the background level content of minerals or heavy metals in soil based on soil worldwide average documented by Barbalace (2007) and Sharma et al. (2016) were adopted. The C_f values within 0.5 to 1.5 implies that the investigated minerals and heavy metals levels are within their original status while C_f values above 1.5 implies an elevation due to anthropogenic activities like industrialization or natural process like volcanic eruption (Itodo et al., 2018). The definition of magnitude of enrichment and contamination includes: low contamination for C_f value < 1; moderate contamination for C_f ≥ 1 to < 3; considerable contamination for C_f value ≥ 3 to < 6 and very high contamination for C_f value ≥ 6 (Rahman et al., 2012).

RESULTS AND DISCUSSION

Soil quality parameters

The soil quality parameters obtained from TSP are presented in Table 1, revealing a mean pH of 8.86 ± 0.14, indicating that the soil is appreciably alkaline (8.50 – 9.00) according to the United States Department of Agriculture (USDA) classification (Motsara & Roy, 2008). The high soil pH value implies a relative restriction of mineral and heavy metal mobility for plant uptake. In nature, higher soil pH may result from alkaline-rich weathered parent material or human activities like the application of alkaline-rich soil amendments and can be adjusted by the introduction of slightly acidic fertilizers (Agbaji et al., 2015). The control soil sample CSP has a pH value of 8.20 ± 0.20, revealing no significant difference from that of the test soil ($p < 0.05$).

Table 1. Soil quality parameters

Parameter/Sample	TSP	CSP
pH	8.86 ± 0.14	8.20 ± 0.20
Organic Carbon (%)	1.45 ± 0.106	0.33 ± 0.04
Nitrogen (%)	0.19 ± 0.03	0.047 ± 0.006
Available Phosphorus (mg/kg)	15.30 ± 0.45	11.13 ± 0.03
ECEC (cmol/kg)	28.50 ± 0.76	6.740 ± 3.48
Soil textural class	Sandy loam	Sandy loam

The mean percentage organic carbon content of TSP was 1.45 ± 0.106%, falling within the moderate level (1.00 – 1.50 %). The organic matter content of TSP was proportional to the organic carbon content. The moderate organic matter, alongside the alkaline nature of TSP, will further restrain mineral and heavy metal mobility, such as nitrogen, available phosphorus, and iron, among others.

There is no significant variation in organic carbon content between the CSP and TSP compared to the test soil ($p < 0.05$).

The mean percentage nitrogen content of TSP was 0.19 ± 0.03 %, falling within the moderate range (0.10 – 0.20 %); while the 15.28 ± 0.45 mg/kg content of available phosphorus in TSP approximately falls within the 6 – 15 mg/kg (low) USDA and Natural Resources Conservation Service (NRCS) classification. However, the 28.50 ± 0.76 cmol/kg mean

ECEC of TSP was quite high (> 25.00 cmol/kg), and in conjunction with the sandy nature of the soil, it will ease the relative immobilization of minerals and heavy metals due to alkaline pH and organic matter content (USDA, 1993; Ross, 2009; Al-Saedi et al., 2016). There is no significant variation in ECEC and available phosphorus content between the CSP and TSP ($p < 0.05$).

Mineral and heavy metal content

The mineral and heavy metal content (mg/kg) in the soil within the pharmaceutical industries is presented in Table 2. The mean magnesium content was 555.02 ± 2.87 mg/kg in TSP. Magnesium is a macro element used in pharmaceuticals as an antacid in relatively large amounts (Kumar et al., 2021; Garg et al., 2022). The mean content of total zinc in TSP was 207.86 ± 1.07 mg/kg, which is less than the 287.99 mg/kg recorded in soils around an automobile workshop in Iworoko-Ekiti, as well as below the 250 mg/kg guideline, indicating that the area is not contaminated based on United Nations Environmental Protection Agency stipulations (Oketayo et al., 2022). The CSP has a Mg content of 0.06 mg/kg, revealing a significant difference from that of the test soil ($p > 0.05$).

Table 2. Mineral and heavy metal content (mg/kg) in soil within pharmaceutical industries

Mineral/Heavy Metal	Magnesium	Zinc	Silicon	Lead	Iron	Aluminum
TSP	555.02 ± 2.87	207.86 ± 1.07	173.90 ± 0.13	38.32 ± 0.13	18348 ± 98.43	4480.40 ± 26.52
CSP	0.06 ± 0.00	52.06 ± 0.45	23.30 ± 0.60	ND	16665 ± 107.22	0.59 ± 0.01
Bn	19000	75.00	277,100	14.00	41000	82000

B_n is the Background levels (Barbalace, 2007; Sharma et al., 2016).

The mean silicon content (173.9 ± 0.13 mg/kg) obtained in soils around the Pharmaceuticals Company was more than eight times the 23.3 mg/kg found in the control sample, suggesting a statistical variation ($p > 0.05$). The relatively high level of silicon content in the soil may be due to the abundance of broken glass bottle container litters (silicon compound) in soils around the industry, as well as the coarse nature of the soil aggregate, whose fundamental constituents are silicon (IV) oxide (Tubana et el., 2016). Nevertheless, the silicon content was less than the 277,100 mg/kg geochemical background value of aluminum in the earth's crust (Barbalace, 2007; Sharma et al., 2016).

The TSP had a mean lead content of 38.32 ± 0.13 mg/kg, in contrast to the CSP whose content was below the detection limit of the MP-AES. The mean lead content was greater than the 28.00 mg/kg lower limit found in the topsoil of Ojota, Lagos industrial area, Kaduna, as well as the 12.50 mg/kg Pb content crustal average but below the 157.64 mg/kg mean content of Pb found around the Isolo dumpsite in Lagos (Odukoya, 2015).

There is no significant variation in the mean iron content of TSP (18348 mg/kg) compared to the 16665 mg/kg found in CSP. However, both values were slightly above the 1771.0 mg/kg levels found in soils within the Illela Garage vicinity in Sokoto, Nigeria (Yusuf et al., 2015), and lower than the 39,000 mg/kg to 41,000 mg/kg geochemical background levels of iron on the earth's crust (Barbalace, 2007; Sharma et al., 2016).

The mean aluminum content in TSP (4480.4 mg/kg) was significantly higher than the 0.59 mg/kg levels of CSP, likely due to the widespread usage of aluminum compounds in pharmaceutical products such as antacids, buffered aspirin, preservatives, fillers, and coloring agents (Krewski et al., 2007). Even though the content was less than 5860 mg/kg, as reviewed for soil samples from different parts of Abuja metropolis (Algattawi et al., 2018). Aluminum, with its compounds, makes up nearly 8.00 % of the Earth's crust, naturally occurring as aluminum silicates, cryolite, and aluminum oxide (bauxite) (Krewski et al., 2007).

Pollution Indices

The pollution indices, in terms of the geo-accumulation index, recorded values of -5.68, -11.22, -1.75, and -4.77 for Mg, Si, Fe, and Al, respectively, falling below zero. This indicates that the soil was uncontaminated by these elements, as displayed in Figure 3. However, the geo-accumulation index for Zn (0.885) and Pb (0.867) falls within the range of uncontaminated to moderately contaminated by Zn and Pb, respectively (Shaari et al., 2015). The control sample shows no contamination by both minerals and heavy metals under investigation.

Similarly, the contamination factors for Mg (0.0290), Si ($6.28 \cdot 10^{-4}$), Fe (0.447), and Al (0.054) shown in Figure 4 remained generally lower than one, indicating low contamination by these elements.

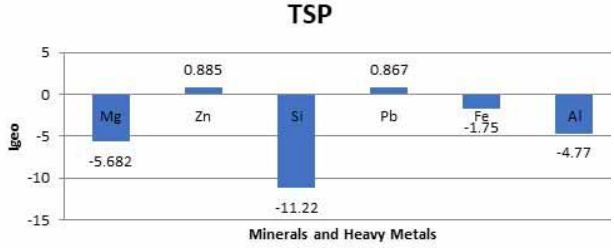

Figure 3. Index of geo-accumulation of mineral and heavy metals in soil

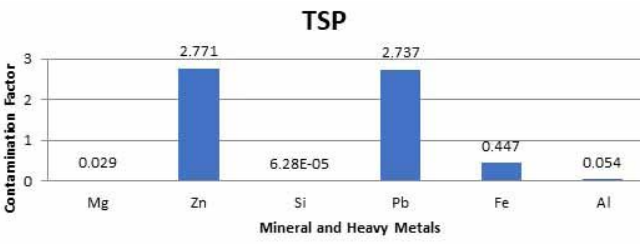

Figure 4. Enrichment factor of mineral and contamination factor of heavy metals

However, the contamination factors for Zn (2.77) and Pb (2.73) fall within the range of (≥ 1 to < 3) (Rahman et al., 2012), suggesting moderate contamination by Zn and Pb, respectively. The control sample exhibits low contamination for both minerals and heavy metals under investigation.

CONCLUSION

The soils in the vicinity of pharmaceutical production operations contain abundant minerals and heavy metals in the following magnitude: Fe > Al > Mg > Zn > Si > Pb. The concentrations of Mg, Si, Fe, and Al in the soil were below the geochemical

background concentration, except for Zn and Pb, whose concentrations were above. Their pollution indices, in terms of geo-accumulation index and contamination factor, indicate moderate contamination. Although there is statistical variation in mineral and heavy metal levels between the test soil and the control soil sample. In conclusion, the pharmaceutical companies under review have not significantly impacted the environment, as Pb compounds are not employed as raw materials. The moderate organic carbon content (1.45 %) alongside the alkaline nature (pH 8.86) of the TSP may further restrain the mobility of minerals and heavy metals such as available phosphorus, zinc, lead, and iron, among others. However, the high ECEC (28.50 ± 0.76 cmol/kg) in conjunction with the sandy nature of the soil may facilitate relative immobilization due to the alkaline pH and organic matter. Environmental impact assessments of the industries and their surroundings should be conducted regularly to monitor contamination levels that may require intervention. Further studies are recommended to investigate the levels of heavy metals in pharmaceutical effluents and the levels of PAH from waste incineration to the surrounding areas.

Declaration of conflicting interest

The authors hereby declare that there is no known conflicting interest anywhere that have interfere with the report in this study.

Contributions

Conceptualization: E.A.Y.; Data curation: E.A.Y.; Funding acquisition: E.A.Y., M.A.A.; Investigation: E.A.Y.; Methodology: E.A.Y.; Resources: E.A.Y.; Supervision: M.A.A.; Validation: M.A.A.; Writing – original draft: E.A.Y.; Writing – review & editing: M.A.A.

Additional information

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