

## **Heavy Metal Contamination of Pharmaceutical Products commonly sold in Nigeria**

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### **Abstract**

The study evaluates the contamination by heavy metals of pharmaceuticals commonly used in Nigeria. Pharmaceutical samples in sixteen pharmacological groups in different dosage forms were purchased from registered pharmacies and patent medicine shops from Abraka and Obiaruku in Delta State, Nigeria. The samples were digested using a bi acid mixture of HNO<sub>3</sub> and HClO<sub>4</sub> in the ratio of 6:1 and analyzed using the Atomic Absorption spectrometer (AAS) for the presence of lead, chromium, cadmium, zinc, nickel, manganese, iron, copper and cobalt. The result reveals significant contamination by all the metals investigated with the exception of copper and cobalt. The contamination may be attributed to wear and tear of manufacturing machinery, contamination from water, packaging and raw materials. It is recommended that machinery used for the manufacture of pharmaceuticals should be well maintained and replaced where necessary and strict adherence to good manufacturing practice (GMP) as required by regulatory agencies.

**Keywords:** *Pharmaceutical, Heavy metals, Contamination, Product*

### **INTRODUCTION**

Twenty four percent of global disease burden for adults and children under the age of five is caused by environmental exposures (WHO, 2015). In Nigeria, forty four percent of deaths is traceable to poor environment (Pona et al., 2021). A potent but often ignored environmental factor that affects all quality of life is the inevitable use of pharmaceutical products. Pharmaceuticals are products of medical and industrial advances used for the diagnosis, treatment and prevention of diseases and ailments, which have replaced to a large extent our reliance on crude herbal preparations.

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Most pharmaceutical products are made by the synthesis of chemicals both organic and inorganic. Relatively few are derived from plants and animal sources. As a result, many of the most effective pharmaceuticals and diagnostic agents that have been introduced into medicine over the last few decades are metal based. Today drugs employing heavy metals have been extremely effective for cancer treatment and other life threatening diseases (Rafati et al., 2013).

A majority of the population invariably use pharmaceutical products almost daily either as food supplements, analgesic, antihypertensive etc. Sustained exposure of our body to heavy metals will lead ultimately to the accumulation of toxins in our tissues and organs causing nutritional deficiencies, hormonal imbalances, neurological disorders, autoimmune reactions, cancer, and other chronic pathological conditions (Pham-Huy *et al.*, 2008). Infact heavy metal toxicity maybe the root of many health disorders today. Heavy metal ion produces large quantities of free radical compounds, which destroys lipids, proteins and DNA in the cellular system (Pham-Huy *et al.*, 2008).

Free radicals damage our cells, prevent cell stabilization and create an overly acidic terrain in the body (Young and Woodside, 2001). Also heavy metals cause the body to produce cholesterol and prevent the absorption of calcium and the more free heavy metal ions in the body, the more buildup of acidic waste and hence the more calcium is deposited in the arteries (Jyothi, 2020). Tchounwou et al. (2012) reported that the threat heavy metal toxins pose to our health is beginning to gain attention. However, heavy metal toxicity is a condition that often goes overlooked in traditional medical diagnosis. While it is rare for an individual to experience a disease or health condition solely from a heavy metal toxin, it is reasonable to conclude that these toxins exert a dramatic effect on the health of an individual and contribute to the progression of many different debilitating conditions (Tchounwou et al., 2012).

Moreover, taking ill and our ability to recover from one is almost always traceable to biochemical reactions in the body with heavy metals playing a significant role. Moreover, heavy metals can interact with pharmaceuticals in the body to alter their pharmacological effects (Sarkar and Sen, 2015). The interaction of aluminum ions with tetracycline to reduce the absorption of the latter is well known. Hence physical and pharmacological interactions between drugs and heavy metals Onyeloni, S.O. (2022). Heavy Metal Contamination of Pharmaceutical Products commonly sold in Nigeria. Madonna University Journal of Medicine and Health Sciences. 2(2): 10-21

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may lead to altered biological actions, prolonged side effects through delayed tubular excretion and biotransformation. Such interactions may also results in anaphylactic reactions and other untoward forms of drug effects leading to cumbersome management of diseases and hospital induced illness (Mannesse *et al.*, 2000).

The term “heavy metal contaminants in pharmaceuticals” may seem a misnomer in some cases considering the fact that heavy metals are currently used in pharmaceuticals for therapeutic purposes (Sarkar and Sen, 2015). For example, aluminum as the hydroxide is used as an antacid for relieving the symptoms of peptic and other forms of hyperacidity. Selenium and copper are employed as nutritional supplements because of the belief that they have a functional role in haemoglobin formation. However, heavy metals found in pharmaceutical products where they are not expected to play any therapeutic role and in excess of the desired quantity when used therapeutically may be regarded is a contaminant (Sarkar and Sen, 2015).

In tablets, contamination may occur from raw materials, active ingredients, excipients e.g. corn starch used as binders, magnesium stearate used as lubricants, disintegrants and lactose used as fillers. Contamination may also occur during granulation including sieving, granular flow from hopper to the die for compression. The sieve, hopper, die and punch in a tableting machine are all made of stainless steel and therefore potential sources of contamination. Liquid preparations, creams, ointments, liniments e.t.c may be contaminated by the raw materials,, active ingredients and excipients (sugar, suspending agents, ointment bases usually petroleum jelly, emulsifiers, water, \preservatives, oil, surfactants etc).

## **MATERIALS AND METHODS**

### **Sampling**

One Hundred (100) samples of various brands of pharmaceuticals from sixteen pharmacological classes in different dosage forms were purchased from pharmaceutical shops and patent medicine stores in Abraka and Obiaruku in Delta State, Nigeria. The sample were manufactured in Nigeria, India and China. None of the sample have expired and are all registered with the National Agency

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for Food and Drug Administration and Control (NAFDAC) in Nigeria. The pharmacological therapeutic classes of pharmaceutical products purchased include the following:

- i. Analgesics
- ii. Antimicrobials
- iii. Antimalarials
- iv. Antihypertensives
- v. Antidiabetics
- vi. Anthelmintics
- vii. Antituberculosis
- viii. Anticonvulsants
- ix. Antidiarrhoeas
- x. Antipsychosis
- xi. Antiasthmatics
- xii. Haematmics
- xiii. Antiulcers
- xiv. Antihistamines
- xv. Corticosteroids
- xvi. Contraceptives

### **Chemicals and Reagents**

The perchloric acid and concentrated nitric acid used were of analytical grade. They were manufactured by Merck Kga A of Germany and BDH Limited Poole, England respectively. The distilled water used was double distilled (DD).

### **Sample Preparation**

Two grams (2g) of sample was accurately weighed on electronic balance into an Erlenmeyer Flask 2ml of perchloric acid and 12ml of concentrated nitric acid are added into the flask The bi-acid digested mixture was heated on a hot plate in a fume cupboard and the temperature maintained at 122°C until dense white fumes appear. The flask was then allowed to cool to room temperature.

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50 ml of distilled water was then added and digestion continued until a clear solution was formed. The solution was cooled and made up to 50 ml with distilled water (Ibe et al., 2017).

### Chemical Analysis

The levels of metals (Cd, Pb, Ni, Cr, Cu, Co, Fe, Mn and Zn) contaminants in the sample solutions were analyzed using atomic absorption spectrometry (Analyst 200, Norwalk CA, USA).

### Quality Control/Assurance

The laboratory table and glass wares were thoroughly cleared to avoid cross contamination. Blank was used to correct instrument readings and spike recovery method was used to check the analytical procedure. The spike recovery achieved for the metals were greater than 89.4%.

### Statistical Analysis

Analysis of variance (ANOVA) was used to test for the difference within the same pharmacological groups studied and lukep test was used to compare differences in the mean concentrations.

## RISULTS

The study of heavy metal contamination in pharmaceutical samples purchased are presented below in Tables 1 to 6.

**Table 1: Levels of heavy metal contamination (µg/g) in some brands of analgesics**

S/ N	ANALGESICS (A)	Brand Code	Pb	Cd	Cr	Ni	Mn	Fe	Zn	Cu	Co
1	Tcb, Ibuprofen 200mg/Tab Paracetamol 500mg Caffeine 50mg	A1	Nd	Nd	1.9	0.5	1	224.0 3	10.5 3	1.55	3.45
2	Cap Indomethacin 25 mg	A2	11.0	0.2	2.7	3.1	22.9	8	7.18	2.75	2.58
3	Cap Piroxican 20mg	A3	0 3.00	Nd	8.8	1.7	3	170.1 1	Nd	0.12 5	Nd

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4	Cap Piroxicam 20mg	A4	Nd	0.4	Nd	1	2.6	1902 1	6.12	0.3	Nd
5	Cap Piroxicam 20mg	A5	Nd	Nd	0.6	Nd	Nd	50.3	2.11	0.55	0.73
6	Tab Aspirin 300 mg	A6	17.1	Nd	9.4	0.6	27.7	6.7	23.1	8.32	2.58
7	Cap Tramadol 50mg	A7	Nd	0.2	Nd	Nd	Nd	24.81	Nd	0.1	Nd
8	Inj Diclofenac 75mg	A8	Nd	2.4	0.2	5	1.7	27.73	38.4 2	1.4	8.93
9	Pu/v Aspirin 760mg/Caffeine 60mg	A9	Nd	Nd	Nd	1.7	3	36.28	14.4 3	2.75	Nd
10	Tab Diclofenac 100mg	A10	2.5	Nd	3.6 3	1.8	0.8	31.93	7.35	40	0.05
11	Tab Ibuprofen 400mg	A11	3.6	Nd	3.4	2.1	4.23	162.0 5	7.35	1.18	2.93
12	Tab Ibuprofen 400mg	A12	6.1	Nd	Nd	3.7	11.1	67.05	5.93	0.63	1.95
13	Tab Ibuprofen 400mg	A13	43.5	1.6	1.8	14. 4	4.93	34.13	8.13	2.3	0.45
14	Cap Ibuprofen 200mg/ Paracetamol 500mg/Caffeine 50mg	A14	Nd	1	24. 4	4.4	28.7	29.3	2.85	Nd	Nd
15	Tab Paracetamol 500mg	A15	Nd	Nd	7.9	0.7	1.5	81.2	9.12	2.06	Nd
T	Tab Paracetamol 500mg	A16	1.1	Nd	3.8	1	1.33	34.13	7.73	2.3	0.45
17	Tab Paracetamol 500mg	A17	Nd	Nd	Nd	Nd	1.2	109.5 6	4.6	3.6	Nd
18	Tab Paracetamol 500mg	A18	Nd	1.1	Nd	1	2.1	19.56	0.83	0.18	Nd
19	Tab Paracetamol 500mg/Aspirin 300mg	A19	Nd	Nd	1.4	0.5	2.0	52.83	3.21	13.3	Nd
		<b>Mean</b>	<b>4.62</b>	<b>0.7</b> <b>8</b>	<b>3.6</b> <b>8</b>	<b>2.2</b> <b>7</b>	<b>6.3</b>	<b>82.98</b>	<b>8.37</b>	<b>4.39</b>	<b>1.27</b>

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31	Tab 250mg	Erythromycia	AM12	Nd	Nd	Nd	Nd	1.3	50.13	6.12	3.11	Nd
32	Inj	Genticia 280mg	AM13	4.2	Nd	1.2	4.6	6.5	49.3	6.63	4.5	Nd
33	Tab	Griseofulvin 500mg	AM14	3.3	0.02	0.6	1.7	22.9	11.48	3.23	1.3	0.3
34	Cap	Lincomycin 500mg	AM15	0.5	0.05	1.7	2.4	2.7	30.1	7.5	1.58	0.48
35	Tab 200mg	Metronidazole	AM16	4.9	0.03	3.6	5.5	3.1	99.33	8.93	1	2.73
36	Tab 400mg	Metronidazole	AM17	Nd	Nd	Nd	1.8	8.3	48.05	1.63	0.05	Nd
37	Tab 400mg	Metronidazole	AM18	0.02	Nd	2.7	1.3	1.8	36.4	15.1	2.43	Nd
38	Nystatin 100,000iu	Pessaries	AM19	1.6	Nd	Nd	1.4	3.2	358	7.18	13.28	Nd
39	Penicillin Ointment 10,000iu	Skin	AM20	6.90	0.6	Nd	1.2	0.9	29.48	8.65	0.23	Nd
40	Cap	Tetracycline 250mg	AM21	4.9	Nd	3.5	5.5	7.8	48.2	3.88	1.08	0.88
			<b>Mean</b>	<b>1.85</b>	<b>0.13</b>	<b>1.92</b>	<b>2.01</b>	<b>5.93</b>	<b>59.21</b>	<b>5.46</b>	<b>2.33</b>	<b>0.27</b>
			<b>S.D</b>	<b>2.34</b>	<b>0.26</b>	<b>3.45</b>	<b>1.21</b>	<b>31.93</b>	<b>72.06</b>	<b>3.49</b>	<b>3.39</b>	<b>0.62</b>

**Table 3: Levels of heavy metal contamination ( $\mu\text{g/g}$ ) in some brands of antimalarials and antihypertensives**

S/N	ANTIMALARIALS (AL)	Brand Code	Pb	Cd	Cr	Ni	Mn	Fe	Zn	Cu	Co
41	Inj. Chloroquine 40mg/ml	AL1	1.1	Nd	0.8	250	2.6	80.83	14.58	3.13	Nd

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42	Cap Chloroquine Phosphate 400mg	AL2	1.1	Nd	0.8	4.1	4.1	8.83	4.34	8.83	Nd
43	Syr Artemether/Lumefantrine	AL3	Nd	Nd	6.0	Nd	6.1	305.25	11.7	11.2	Nd
44	Tab. Amodaquine 200mg	AL4	1.1	0.6	2.1	0.9	5.2	78.25	9.14	5.13	Nd
45	Tab Artesunate 50mg	AL5	7.6	0.3	Nd	2.3	11.5	50.25	4.58	3.85	1.2
46	Tab Quinine 300mg	AL6	9.6	0.8	4.3	6.1	3.5	31.17	262	5.23	5.3
47	Tab. Sulphadoxine 500mg /Pyrimethamine 75mg	AL7	Nd	Nd	4.1	4.4	3.7	112.3	12.13	2.15	Nd
48	Tab. Arthemether/lumenfantrine 20mg /Luemantrine 120mg	AL8	1.6	0.05	Nd	1.4	3.2	51.11	6.3	1.19	0.9
		<b>Mean</b>	<b>2.76</b>	<b>0.22</b>	<b>2.26</b>	<b>2.68</b>	<b>4.98</b>	<b>59.11</b>	<b>8.17</b>	<b>5.09</b>	<b>0.93</b>
		<b>S.D</b>	<b>3.49</b>	<b>0.32</b>	<b>2.27</b>	<b>1.99</b>	<b>2.86</b>	<b>19.32</b>	<b>0.06</b>	<b>1.1</b>	<b>2.67</b>

**ANTIHYPERTENSIVE  
(AH)**

49	Tab Apresoline 25mg	AH1	Nd	Nd	Nd	1.3	3.4	20.50	2.60	4.15	Nd
50	Tab Captopril 25mg	AH2	0.6	0.8	0.5	3.7	3.8	60.93	3.9	5.13	Nd
51	Tab 1-hydrochlorothiazide 50mg/ Amelorida 75mg	AH3	6.2	0.4	0.5	3.9	12.1	41.25	1.24	0.025	2.35
52	Tab Hydrochlorothiazide 50mg/ Amoloridc 75mg	AH4	4.3	Nd	0.7	3.1	14.6	51.15	3.12	1.5	Nd
53	Tab Methyldopa 250mg	AH5	1.3	0.1	Nd	0.8	1.1	6.2	6.53	543	Nd
54	Tab Methyldopa 250mg	AH6	0.2	Nd	0.1	1.4	1.7	37.45	- 6.88	2.45	Nd
55	Tab Methyldopa 250mg	AH7	1.2	Nd	T	1,4	1	28.83	5.28	4.14	Nd
56	Tab Methyldopa 250mg	AH8	15.3	0.4	5.8	6.8	37.5	252	7.08	6.96	4.9

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57	Tab Hydrochlorothiazide 50mg	AH9	Nd	0.4	Nd	0.6	0.7	8.8	4.1	5.15	Nd
58	Tab Nifedipine 20mg	AH10	3.9	Nd	2,9.7	15.7	1.8	27.8	4.78	0.88	1.95
59	Tab Nifedipine 20mg	AH11	1.7	Nd	Nd	1.7	12	37.45	17.4	15.78	Nd
60	Tab Methyldopa 250mg	AH12	22.2	Nd	1.6	0.9	2.9	46.33	3.95	3.44	Nd
61	Tab Captopril 25mg	AH13	Nd	Nd	2.8	2	20	144.13	6.45	0.53	0.68
62	Tab Methyldopa 250mg	AH14	4.3	0.5	Nd	1.6	1.3	24.8	8.63	0.55	Nd
		<b>Mean</b>	<b>4.34</b>	<b>0.19</b>	<b>3.05</b>	<b>3.2</b>	<b>6.86</b>	<b>58.9</b>	<b>5.33</b>	<b>4.69</b>	<b>0.76</b>
		<b>S.D</b>	<b>6.56</b>	<b>0.26</b>	<b>7.83</b>	<b>3.96</b>	<b>9.99</b>	<b>67.3</b>	<b>2.05</b>	<b>4.37</b>	<b>1.48</b>

**Table 4: Levels of heavy metal contamination ( $\mu\text{g/g}$ ) in some brands of antidiabetes, anthelmintics, antituberculosis and anticonvulsants**

S/N	ANTIDIABETES (AD)	Brand code	Pb	Cd	Cr	NI	Mn	Fe	Zn	Cu	Co
63	Tab Chlorpropamide 250mg	AD1	3.9	Nd	N d	1.1	8.5	30.13	8.23	6.23	0.55
64	Tab Glipizide 5mg	AD2	Nd	0.1	Nd	1.3	4.6	31.48	3.63	0.53	Nd
65	Tab Glucophapo 250mg	AD3	11	0.8	0.9	1.5	1.3	24.78	3.43	7.63	Nd
66	Tab Glipizide 5mg	AD4	30.2	0.2	9.5	8.2	8.0	329.8	25.23	1.73	2.8
67	Metformin 250mg	AD5	Nd	9.3	Nd	1.5	1.0	49.9	4.83	2.4	Nd
		<b>Mean</b>	<b>9.02</b>	<b>0.28</b>	<b>2.08</b>	<b>2.72</b>	<b>4.68</b>	<b>43.22</b>	<b>9.07</b>	<b>3.7</b>	<b>0.67</b>
		<b>S.D</b>	<b>11.83</b>	<b>0.31</b>	<b>4.03</b>	<b>3.07</b>	<b>3.56</b>	<b>134.10</b>	<b>2.04</b>	<b>0.65</b>	<b>2.17</b>
<b>ANTHELMINTICS (AT)</b>											
68	Tab. Levamisole 40mg	AT1	0.03	Nd	1.6	Nd	4.2	60.9	16.2	23.73	Nd
69	Tab Mebendazole 100mg	AT2	9.8	0.2	5.6	4.9	39.8	408.25	0.48	0.18	4.55
70	Tab Pyrantel Pamoate 100mg	AT3	15.7	1.2	12.6	37.4	6.4	53.93	8.11	1.53	2.75

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			<b>Mean</b>	<b>10.51</b>	<b>0.47</b>	<b>6.4</b>	<b>14.1</b>	<b>16.8</b>	<b>174.36</b>	<b>8.26</b>	<b>8.48</b>	<b>2.43</b>
			<b>S.D</b>	<b>4.87</b>	<b>0.64</b>	<b>5.63</b>	<b>20.32</b>	<b>19.95</b>	<b>121.17</b>	<b>3.72</b>	<b>3.87</b>	<b>0.4</b>
<b>ANTITUBERCULOSIS</b>												
<b>(AC)</b>												
71	Tab Ethambutol 500mg Pyrazinamide 150mg Isonizide 150mg/Rifampicin 300mg	AC1	Nd	0.2	1.9	1.9	2.6	114.3	2.28	Nd	Nd	
72	Tab Isoniazide 150mg	AC2	8.3	Nd	2.4	3.9	15.9	1042	1.19	0.03	1.1	
73	Tab Comb Dot	AC3	Nd	Nd	1.4	0.4	2.0	52.83	0.36	41.2	Nd	
74	Cap Rifampicin 300mg	AC4	0.09	Nd	0.1	1.5	2.6	4120	1.66	1.10	Nd	
		<b>Mean</b>	<b>2.11</b>	<b>0.05</b>	<b>1.45</b>	<b>1.9</b>	<b>5.78</b>	<b>90.44</b>	<b>1.28</b>	<b>13.74</b>	<b>0.37</b>	
		<b>S.D</b>	<b>4.16</b>	<b>0.1</b>	<b>0.18</b>	<b>1.4</b>	<b>6.76</b>	<b>32.96</b>	<b>0.96</b>	<b>23.78</b>	<b>0.64</b>	
<b>ANTICONVULSANTS</b>												
75	Tab Carbamazepine 200mg		1.8	0.7	6.5	2.7	6.1	98.16	17.82	1.7	Nd	
76	Tab Phenobarbitone 30mg		9.9	0.3	1.8	7.7	4.4	133.77	33.25	1.38	3.85	
77	Cap Phenytoin 100mg		3.8.	Nd	1.8	2.7	23.2	204.85	16.63	1.55	0.83	
		<b>Mean</b>	<b>5.17</b>	<b>0.33</b>	434	<b>4.2</b>	<b>11.23</b>	<b>145.59</b>	22.57	1.54	1.56	
		<b>S.D</b>	<b>4.22</b>	<b>0.35</b>	2.37	<b>2.6</b>	<b>10.4</b>	<b>54.33</b>	9.32	0.17	2.03	

**Table 5: Levels of heavy metal contamination ( $\mu\text{g/g}$ ) in some brands of antidiarrhoea, antipsychosis, antiastimatics, haematinics and antiulcers**

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S/N	ANTIDIARRHOEA (AR)	Brand name	Pb	Cd	Cr	Ni	Mn	Fe	Zn	Cu	Co
78	Tab Loperamide 4mg	AR1	6.7	Nd	5.3	3.3	26.6	261.14	11.22	0.03	2.23
79	Oral Rehydration Salt	AR2	Nd	1	4.4	2.4	28.7	224.03	10.53	1.56	3.45
		<b>Mean</b>	<b>3.35</b>	<b>0.5</b>	<b>4.85</b>	<b>3.85</b>	<b>27.65</b>	<b>242.59</b>	<b>10.88</b>	<b>0.78</b>	<b>2.84</b>
		<b>S.D</b>	<b>4.73</b>	<b>0.71</b>	<b>0.63</b>	<b>0.77</b>	<b>1.48</b>	<b>26.21</b>	<b>0.68</b>	<b>1.08</b>	<b>0.86</b>
<b>ANTIPSYCHOSIS (AC)</b>											
80	Tab chlorpromazme 50mg	AC1	10.6	0.3	6.6	4.8	36.2	97.23	24.19	0.83	1.45
81	Tab triflouoperazine 5mg	AC2	7.2	0.1	3.9	5.0	11.2	67.33	20.0	1.18	1.78
		<b>Mean</b>	<b>8.9</b>	<b>0.2</b>	<b>5.25</b>	<b>4.9</b>	<b>23.7</b>	<b>82.28</b>	<b>22.09</b>	<b>1.01</b>	<b>1.62</b>
		<b>S.D</b>	<b>2.4</b>	<b>0.14</b>	<b>1.91</b>	<b>0.14</b>	<b>17.68</b>	<b>21.14</b>	<b>2.93</b>	<b>0.25</b>	<b>0.23</b>
<b>ANTIASTMATICS (AA)</b>											
82	Tab Aminophylline 100mg	AA1	10.6	0.3	0.3	4.5	12	53.93	8.4	15.73	2.75
83	Tab Salbutamol 4mg	AA2	6.8	Nd	0.4	3	53.6	200.73	7.83	13.21	2.43
84	Tab Salbutamol 2mg	AA3	1	2.3	1.1	10	1.5	39.78	3.5	1.53	Nd
		<b>Mean</b>	<b>6.13</b>	<b>0.87</b>	<b>0.6</b>	<b>2.87</b>	<b>22.37</b>	<b>98.15</b>	<b>10.16</b>	<b>10.16</b>	<b>1.73</b>
		<b>S.D</b>	<b>4.83</b>	<b>1.25</b>	<b>0.44</b>	<b>1.7</b>	<b>27.55</b>	<b>89.12</b>	<b>2.68</b>	<b>7.58</b>	<b>1.5</b>
<b>HAEMATINICS (H)</b>											
85	Tab Ferrous Sulphate 300mg	H1	0.7	0.044	4.7	2.8	15.7	305.19	10.5	16.63	0.3
86	Cap Iron/Multivitamin/Minerals	H2	Nd	Nd	1.7	2.6	Nd	224.9	3.48	1.63	1.16

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7	Cap Iron/Multivitamin/Minerals	H3	Nd	Nd	Nd	Nd	30.5	154.08	5.53	2.81	Nd
88	Tab Vitamin B complex	H4	Nd	2.1	Nd	1.5	12.2	160.12	7.11	3.2	Nd
89	Tab Multivite	H3	0.5	Nd	3	2.2	9.1	89.62	1.1	2.06	1.01
		<b>Mean</b>	<b>0.24</b>	<b>0.43</b>	<b>1.88</b>	<b>1.82</b>	<b>13.5</b>	<b>186.78</b>	<b>5.54</b>	<b>5.27</b>	<b>0.49</b>
		<b>S.D</b>	<b>0.34</b>	<b>0.93</b>	<b>2.02</b>	<b>1.14</b>	<b>11.15</b>	<b>82.6</b>	<b>3.57</b>	<b>6.39</b>	<b>0.56</b>
<b>ANTIULCERS (AV)</b>											
90	Tab Cimetidinc 400mg	AV1	2.0	Nd	Nd	2.0	7.6	109.55	4.60	3.60	Nd
91	Cap Omeprazole 20m g	AV2	Nd	0.4	Nd	0.8	1.2	33.83	4.16	16.5	Nd
92	Tab Ranitidine 150mg	AV	Nd	0.1	Nd	0.5	3.8	178.6	9.68	11.23	Nd
		<b>Mean</b>	<b>0.67</b>	<b>0.17</b>	<b>0.0</b>	<b>1.1</b>	<b>4.2</b>	<b>107.3</b>	<b>6.15</b>	<b>10.44</b>	<b>0.0</b>
		<b>S.D</b>	<b>1.15</b>	<b>0.21</b>	<b>0.0</b>	<b>0.79</b>	<b>3.22</b>	<b>72.4</b>	<b>3.07</b>	<b>6.49</b>	<b>0.0</b>

**Table 6: Levels of heavy metal contamination ( $\mu\text{g/g}$ ) in some brands of antihistamines, corticosteroids and contraceptives**

S/N	Anthistamines (AM)	Brand name	Pb	Cd	Cr	Ni	Mn	Fe	Zn	Cu	Co
93	Tab. Chlorpheniramine 4mg	AM1	6.6	6.4	14.1	1.7	3.9	77.63	18.23	2.22	3.89
94	Tab. Chlorpheniramine 4mg	AM2	Nd	Nd	Nd	1.0	2.6	63.6	3.43	2.58	Nd
95	Tab. Cyproheptadine 4mg	AM3	9.1	1.0	4.40	5.40	25.4	81.22	38.43	1.4	8.93
96	Tab. Cyproheptadine 4mg	AM4	25.9	3.1	13.9	13.2	24.4	113.68	8.63	2.85	4.55
		<b>Mean</b>	<b>10.4</b>	<b>2.63</b>	<b>8.1</b>	<b>5.33</b>	<b>14.08</b>	<b>84.03</b>	<b>17.18</b>	<b>2.26</b>	<b>4.34</b>
		<b>S.D</b>	<b>11.02</b>	<b>2.83</b>	<b>7.05</b>	<b>5.59</b>	<b>12.52</b>	<b>21.18</b>	<b>16.55</b>	<b>0.65</b>	<b>3.65</b>

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### CORTICOSTEROIDS

(C)

97	Tab. Prednisolone 5mg	C1	Nd	Nd	Nd	nd	1.1	39.9	6.88	3.95	Nd
98	Tab. Dexamethazone 1mg	C2	Nd	Nd	6.0	Nd	Nd	56.3	7.11	Nd	Nd
99	Tab. Bethametrazone 5mg	C3	1.2	0.91	5.2	3.1	7.1	43.89	6.83	5.82	Nd
		<b>Mean</b>	<b>0.4</b>	<b>0.3</b>	<b>3.73</b>	<b>1.03</b>	<b>2.73</b>	<b>46.64</b>	<b>6.94</b>	<b>3.26</b>	<b>0.0</b>
		<b>S.D</b>	<b>0.69</b>	<b>0.52</b>	<b>3.26</b>	<b>1.79</b>	<b>3.82</b>	<b>8.46</b>	<b>0.15</b>	<b>2.97</b>	<b>0.0</b>

### CONTRACEPTIVES

(CT)

100	Tab. Ethinyestradiol 0.03/ Norgesterone 0.3mg Fenocs Fumerate 75mg		2.7	Nd	2.9	1.8	9.1	141.2	2.83	4.11	3.22
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## DISCUSSION

### Lead

From the study, 61% of all the samples studied shows significant contamination by lead. The level of lead contaminant ranges from 10.15mg/L among anthelmintic to a mean *value* pf 0.24mg/L in haematinics. The value is higher than the level of 0.01 mg/L to 1.08 mg/L obtained by Orisakwe and Nduka (2009) in some paediatrics syrups commonly, used in Nigeria. This may be due to the use of much lower quantity of pharmaceutical samples for analysis, in some cases, less than 500ng as against 2g used in the study. Moreover, tablets and capsules have higher contact with stainless steel materials in the course of their manufacture than the syrups. However, thirty-nine percent (39%) of the samples were below detectable limits (BDL). The contamination levels in 61% are significantly above the National Agency for Food and Drug Administration and Control (NAFDAC) tolerable limit of 0.001 mg/dL. Consequently, these observed values may increase the blood levels of patients with continuous use. Undoubtedly one of the oldest occupational toxins Onyeloni, S.O. (2022). Heavy Metal Contamination of Pharmaceutical Products commonly sold in Nigeria. Madonna University Journal of Medicine and Health Sciences. 2(2): 10-21

as evidence of lead poisoning can be found dating back to Roman times. Some pharmaceuticals such as antidiabetics and some analgesics used by arthritic patients are taken for life.

High levels of lead in the blood may lead to deleterious health consequences like autism; miscarriages and low birth weight of infants (Neda *et al*, 2017). Lead also accelerates ageing process, mental decline, infertility in couples, as it is associated with reduction in sperm count and motility. Other effects are anaemia and hypertension (Kadzung, 2010).

### **Cadmium**

Cadmium contamination level observed in this study ranges from BDL in commonly used oral contraceptive taken daily to a mean value of 2.63 mg/L in antihistamines used for cold and skin allergic reactions. The level is similar to the highest level of 2.45 mg/L obtained by Orisakwe and Nduka (2009). However only a 46% of the samples shows Cd concentrations above the detectable limit. The level of cadmium contamination of pharmaceutical in this study is above the FAO/WHO tolerable daily intake of cadmium of 70 µg to 97 µg for an average body weight of 70kg man (WHO, 2004). Cadmium is absorbed through the - intestinal tract. Cadmium accumulation in the body may lead to clinical manifestation of kidney disorders like proximal tubular dysfunction (Hayes, 1997): Other target organs include bones (Osteomalacia) liver, lung, testis (oligospermea) and haemopoietic systems (anaemia) (Kokak and Akcil, 2006).

### **Chromium**

Chromium is considered to be one of the most environmental toxic pollutant in the world (Oliveir, 2012). Pharmaceutical contamination of chromium in this study ranges from a mean value of 5.10 mg/L in antihistamine to BDL among antiulcers. 68% of the samples shows detectable limits with the highest value of 29.9 mg/L in nifedipine, a commonly prescribed antihypertensive and 24.4 mg/L in ibuprofen/paracetamol/coffeine combination an over — the — counter (OTC) medicine used routinely as an analgesics. Persistence exposure to chromium may result in skin rashes, stomach upset, respiratory disorders, weak immune system, kidney and liver damage, alteration of genetic material, lung and liver cancer and ultimately death. Tolerable limit for chromium is 0.005 mg/L (WHO, 2003).

### **Nickel**

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Nickel is considered a normal constituents of the diet and the dietary intake of nickel in most countries ranges from 100 -300  $\mu\text{g}/\text{day}$  (Cempel and Nickel, 2006). In the pharmaceutical samples considered in this study, nickel level have been found to range from a mean value of 14.1  $\text{mg}/\text{L}$  among anthelmintics to 1.03  $\text{mg}/\text{L}$  in corticosteroids. Therefore, there is detectable level of nickel in all the classes of samples investigated. This may be expected as water generally contains nickel of at a concentration of about 100  $\text{mg}/\text{L}$  (Nielsen *et al.*, 1999). Although, nickel has a bioavailability of 1 – 10% when ingested, high level of nickel is known to cause allergic dermatitis known as nickel itch (Yoshihisa and Shimizu, 2012). Other toxicological effects of nickel exposure include kidney damage, cardiovascular and immune systems and blood disorders (Cornell and Landis, 1984). These effects may occur when nickel is taken above the dietary limit' of 0.187-302  $\text{mg}/\text{day}$ .

### **Manganese**

Manganese as its sulphate is commonly used in pharmaceuticals as food supplements for bone development and is a constituent of enzymes (Siddiqui *et al.*, 2014). This study shows high level of manganese with 96% of the sample having various level of manganese contamination. The highest mean value of 27.65  $\text{mg}/\text{L}$ , was observed in antidiarrhea. The least mean value of 2.73  $\text{mg}/\text{L}$  was recorded among corticosteroids. Despite its human requirement however, high level of manganese may result in health problems. Mild manganese toxicity may lead to manganese psychosis with symptoms of asthenia, anorexia, insomnia, muscular pains, mental excitement hallucinations, unaccountable laughter impaired memory and compulsive actions. Moderate toxicity include speech disorder clumsy movement, abnormal gait, poor balance, hyperplexia in a the lower limbs, and fine tremor severe signs include rigidity, spasmodic laughter and Parkinson type syndrome (Driver *et al.*, 2009; DeMaagd and Philip, 2015). With a daily requirement of 2.5 to 7.0  $\text{mg}$ , the level of manganese contamination in this study is above the tolerable limit.

### **Iron**

Iron has the highest level of contamination of all the metals considered in the study. The highest mean values of 242.58  $\text{mg}/\text{L}$  was seen among the corticosteroids. All 100 % of the samples studied shows high level of iron contamination. This may be the result of wear and tear of the Onyeloni, S.O. (2022). Heavy Metal Contamination of Pharmaceutical Products commonly sold in Nigeria. Madonna University Journal of Medicine and Health Sciences. 2(2): 10-21



manufacturing equipment which are stainless steel composed predominantly of iron. The food and nutrition board (FNB) of the institute of medicine (IM) USA recommended' dietary allowance of 7-10 mg/day for children, 8 mg/day for adult and 27 mg/day during pregnancy for mothers (Cetin *et al.*, 2011). Iron is used for the treatment of iron deficiency anaemia and is stored in the spleen and bone marrow. Injection of large quantity of iron salt may lead to several necrotizing gastritis with vomiting and haemorrhage (Baranwal and Singhi, 2003). Chronic iron toxicity also known as haemochromatosis results when excess iron is deposited in the heart, liver, pancreas and other organs, which may lead to organ failure and - death. The level of iron contamination among pharmaceuticals in this study' may be deleterious to health.

### **Zinc**

Varying level of zinc was found in 98% of the samples studied. The highest mean concentration of 22.57 mg/L was found among anticulvants with the least mean level of 1.28 mg/L among antituberculosis. A trace level of Zn is an essential element in man. The catalytic activities of about one hundred (100) enzymes are zinc dependent in the human body and also participate in cell signaling, release of hormones and apoptosis (Thomas *et al.*, 2014). The recommended dietary allowances are 4 – 5 mg/day, 9 – 13 mg/ day and 13 – 19 mg/day for children, women and men respectively (Dufner-Beattie *et al.*, 2006). Although human body can tolerate high level of zinc, acute zinc toxicity (oral dose of 225 – 450 mg) can causes health problems like stomach cramps, skin irritation, vomiting, nausea and anaemia. Chronic zinc expose may lead to copper deficiency in man and very high level of zinc can damage the pancreas, distort protein metabolizing enzymes and arteriosclerosis. It can be a danger to unborn foetus and breastfeeding mothers as the foetus and children can get exposed through blood and breast milk respectively. The National Research Council (NRC) recommended daily zinc intake between 10 to 20 mg /day (NRC, 1989). It is therefore unlikely that the use of pharmaceuticals considered in this study will result in zinc toxicity.

### **Cobalt**

Among the metals investigated, cobalt have the least level of contamination of only 46%. Cobalt have BDL among antiulcers and corticosteroids and the highest mean value of 4.34 mg/L among Onyeloni, S.O. (2022). Heavy Metal Contamination of Pharmaceutical Products commonly sold in Nigeria. Madonna University Journal of Medicine and Health Sciences. 2(2): 10-21

antihistamines. At low concentration, cobalt plays a prominent role in the formation of cyanocobalamin viz B12. Exposure to high concentration of cobalt may lead to symptoms of cobalt poisoning characterized by visual impairment, hypothyroidism, peripheral neuropathy, rashes, cardiomyopathy, auditory and cognitive impairment (Leysens *et al.*, 2017). Since 50% of ingested cobalt is absorbed through the intestine (Angelescu and Cristiana, 2003), long term use of pharmaceutical contaminated by cobalt may be hazardous. However, cobalt contamination level among pharmaceuticals considered in this study is relatively safe.

### **Copper**

Copper is present in 97% of the samples studied with the lowest mean value of 0.76 mg/L in antidiarrhoea. Antituberculosis has the highest level of contamination with a mean value of 13.74 mg/L. The blood level of copper is about 100 µg/100 ml in adult (Cesar and Fraga, 2005). In humans, copper is necessary for the development of connective tissue, nerve endings and bone. It also participates in iron metabolism. There is about 80 mg of copper in the adult body with the highest concentration in the head and brain. Medium intake of Cu ranges between 1.0 to 1.6 mg/day (Harris, 1997). Chronic copper toxicity is rare in humans and is mostly associated with liver damage. Acute Cu intoxication leads to gastrointestinal effect such as abdominal pain, nausea, diarrhea, vomiting. From the study, Cu contamination level is relatively safe as the risk of acute or chronic, toxicity is most improbable.

### **CONCLUSIONS**

The study of one hundred (100) pharmaceutical samples in sixteen pharmacological and therapeutic classes commonly used in Nigeria shows a significant contamination by heavy metals with the exception of copper and cobalt. Iron has the highest contamination level of 100 % with cobalt of 46% as the least. Therefore repeated use can lead to adverse health effects ranging from minor stomach upset to metal poisoning with lead and chromium being the most dangerous. In addition, untoward drug reactions and drug hypersensitivity reactions may occur. To protect consumers and patients from metal contamination that can undermine the safety and quality of pharmaceutical, drug manufacturing companies must follow strictly Good Manufacturing Practice

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(GMP) by abiding by the strict quality control (QC) standards required by the National Agency for Food and Drug Administration and Control (NAFDAC).

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