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*Original Article*

# Evaluating Lead, Nickel and Copper Levels in Selected Pharmaceutical Products Available in Iraqi Local Market: Analytical and Toxicological Assessment

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**Abstract**

**Introduction:** Lead, Nickel and Copper are widely spread heavy metals that are linked to many harmful effects to human body, they enter the body via food, water environment, pharmaceutical and cosmetic products. Exposure to these heavy metals could cause various organ damage including cardiovascular, neurological, immunosuppression and cancer. The harmful effect could take years or decades to appear. According to the International Council for Harmonization (ICH) it's important to adhere with the permitted daily exposure (PDE) doses of these hazardous elements to avoid the potential health risks. **Methods:** In this study, we investigate the presence of Lead, Nickel and Copper in selected pharmaceutical products collected from local pharmacies in Mosul/ Iraq including four eye drops and six intravenous infusions which considered critical products due to their invasive effect and any contamination will lead to devastating outcomes. According to the maximum daily recommended dose of each product, the maximum ingested amount of Lead, Nickel and Copper were calculated and compared to the permitted daily exposure (PDE) of each metal. **Results:** The results showed that from the ten samples, three IV infusions (M1, M2, M3) contained high levels of Lead ranging from (0.1-0.15) ppm, while one IV infusion (M1) contained high levels of Nickel (5) ppm, Copper levels were within the safe limits in all investigated products. **Conclusion:** 30% of the samples investigated were found to be contaminated with unsafe levels of heavy metals, more research and screening studies should be done to confirm this finding, also such products should have more restricted quality control measures.

***Keywords:*** *Copper; Eye Drops; IV Infusion; Lead; Nickel*

## Introduction

Lead (Pb), nickel (Ni), and copper (Cu) are naturally occurring elements. The consumption of these heavy metals can lead to their accumulation in various vital organs, including the liver, kidneys and brain resulting in a wide range of harmful effects on the human body (Quader *et al.*, 2022). They enter the body through the environment, food, water, medicines, personal care products and plant products. The main sources of environmental pollution with heavy metals are mining, industrial emissions and solid waste. Then heavy metals can emerge to the soil and water through rainfall, leading to extensive soil and water pollution (Yu *et al.*, 2025).

Prolonged exposure may lead to neurological (Chen *et al.*, 2016), cardiovascular (Yang *et al.*, 2020), and immunological (Mishra & Singh, 2020) side effects, as well as cancer (Lawal *et al.*, 2021; Kim *et al.*, 2015). The harmful effect of these heavy metals depends on various factors such as the type of

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metal, the route, the duration of use and the age of the patient. Children are more prone to the toxic effect of these elements compared to elderly people due to their immature body systems (Sohail *et al*., 2024), as Pb toxicity in young age could lead to premature deaths and less IQ points (Kinally *et al*., 2025)

Heavy metals can generally be classified according to their toxicity as follows: toxic heavy metals (As, Cd, Cr, Hg, Ni, and Pb), semi-metal heavy metals (Sb and Bi), and essential non-toxic heavy metals that become toxic at higher levels (Co, Cu, Fe, Mo, Mn, Se, Sn, and Zn). Pharmaceutical products contaminated with heavy metals can cause serious health problems (Chaturvedi *et al*., 2021).

Heavy metals may enter pharmaceutical products through raw materials, water, manufacturing equipment, and/or container closure systems. The ICH provides a safety guideline, ICH Q3D, for assessing and controlling elemental contamination in pharmaceutical products by establishing limits for permitted daily exposure (PDE) in µg/day for each toxic element across different routes of administration (Ulman *et al*., 2012).

In this investigation, we assessed the ammount of Pb, Ni, and Cu in selected pharmaceutical items, including eye drops and IV infusions. Because of their invasive nature, any contamination could be hazardous and may lead to devastating outcomes. For heavy metals, their PDE limits are the same Since both eye drops and parenterals bypass metabolism and cause comparable systemic health issues (Oliveira *et al*., 2023).

**Health Risks**

***Lead (Pb)***

Lead poisoning has irreversible negative effects on various body organs; therefore, its considered a major health concern**.**

some harmful effects include:

- **Neurotoxicity:** Psychological changes reduced IQ in children, cognitive impairment, irritability, and difficulty concentrating (Maria *et al*., 2019).
- **Cardiovascular effects:** Increased risk of hypertension and heart disease (Albakri, 2019; Yu *et al*., 2025).
- **Renal impairment:** Long-term lead exposure can cause kidney damage, potentially leading to renal failure (Upadhyay *et al*., 2024).
- **Reproductive toxicity:** Lead can exert teratogenic effects on the developing fetus (Bellinger, 2005).
- **Hematologic effects:** Continuous exposure may disrupt blood cell production, resulting in severe anemia (Wani *et al*., 2015).

***Nickel (Ni)***

- **Hypersensitivity:** Nickel is a significant allergen and can trigger contact dermatitis (Tramontana *et al*., 2020).
- **Carcinogenicity:** the International Agency for Research on Cancer (IARC) has designated Ni as a Group 1 carcinogen as long-term nickel exposure has been linked to lung cancer (Guo *et al*., 2019).
- **Systemic toxicity:** Ingesting high amounts of nickel may cause nausea, vomiting, diarrhea, and abdominal pain (Begum *et al*., 2022).

***Copper (Cu)***

Pharmaceuitical items contaminated with Cu may have a number of harmful consequences. Although Cu is a necessary trace element and plays an important enzymatic role, consuming high amount of it can be dangerous.

Its toxic effects include:

- **Acute toxicity:** Vomiting, abdominal pain, and—at high exposure levels—organ failure or death.
- **Chronic toxicity:** Long-term exposure may cause liver damage, neurological deficits, cognitive impairment, and anemia (Karim, 2018; Gaetke *et al*., 2014).

**Permitted Daily Exposure (PDE)**

According to the ICH Q3D guideline**,** the maximum quantity of an elemental impurity that is considered safe for daily human exposure over a lifetime expressed in µg/day is termed as Permitted Daily Exposure (PDE).

The purpose of this regulatory concept is to assess limits for heavy metals contamination in pharmaceutical products (Ulman *et al*., 2012).

In this study, the levels of heavy metals in a selected number eye drops and IV infusions were examined. Their PDE limits are the same due to the comparable systemic metabolism and toxicity of such pharmaceuticals (Oliveira *et al*., 2023), and according to the ICH Q3D guideline for these dosage forms, the PDE limits for Pb, Ni, and Cu are **5** µg/day, **20** µg/day, and **340** µg/day, respectively (Ulman *et al*., 2012).

**Methodology**

All reagents utilized in this work were of analytical reagent grade. Pb, Ni, and Cu standard solution were provided by Sigma-Aldrich, Germany. Type 1 water was used for all heavy metal dilutions. Both qualitative and quantitative approaches were used to evaluate Pb, Ni, and Cu levels. The concentration of heavy metals were measured in µg/ml (ppm), and based on the maximum daily dose of each medication**,** the maximum daily intake of each metal was calculated and compared to its respective PDE**.**

**Sample Collection**

Ten pharmaceutical items were selected and purchased from local pharmacies in Mosul, Iraq, in April 2025. Every sample, including four eye drops and six IV infusions, was within its expiration date and they originated from Jordan, Ukraine, Greece, India, Pakistan, Switzerland, and Syria (Liang *et al*., 2014)**.**

**Instrument**

To assess the levels of heavy metals in the selected samples, Graphite Furnace Atomic Absorption Spectrometry (GFAAS) was conducted by using an atomic absorption spectrometer (210 VGP, BUCK Scientific, USA). Detailed methodology is provided in the following references: Inui *et al*. (2012) and Liang *et al*. (2014)**.** The conditions of measurements are listed in Table 1.

***Table 1: Conditions of Measurements of Each Element***

| The conditions of measurements | Heavy metals | | |
|---|---|---|---|
| | Pb | Ni | Cu |
| Wavelength (nm) | 283.3 | 232 | 324.7 |
| Lamp current mA | 7.0 | 6.0 | 1.5 |
| Slit width nm | 0.7 | 0.2 | 0.7 |
| PMT voltage v | 481.0 | 504.9 | 465.3 |

**Results**

The analysis results showed that, of the ten samples, seven samples (70%) were within the safe limits established by the ICH Q3D guideline, while three samples (30%) contained elevated levels of Pb,

including one sample that had unsafe levels of both Pb and Ni. The detailed results are presented in Tables 2, 3, and 4.

***Table 2: Quantitative Pb Analysis Results with Products Information and Maximum Daily Doses (ml)***

| Code | Pharmaceutical product | Active ingredient | Dosage form | Max. Daily Dose (ml) | Pb µg/ml (ppm) | Maximum Daily Consumed Amount of pb (µg/day) |
|---|---|---|---|---|---|---|
| D1 | Apidex/Jordan | Dexamethasone phosphate | Eye drop | 1ml | 0.76±0.001 | 0.76 |
| D2 | Tobracin/Jordan | Tobramycin | Eye drop | 1ml | 0.025± 0.0003 | 0.025 |
| D3 | Ciprofarm/Ukraine | Ciprofloxacin | Eye drop | 1ml | 0.01± 0.002 | 0.01 |
| D4 | Dexachlor/Greece | Dexamethasone/ chloramphenicol | Eye drop | 1ml | 0.01± 0.005 | 0.01 |
| P1 | Dolocetam/India | Acetaminophen 1g/100ml | IV infusion | 400 ml | 0.01±0.003 | 4 |
| P2 | Feveral/Pakistan | Acetaminophen 1g/100ml | IV infusion | 400 ml | 0.01±0.002 | 4 |
| P3 | Paraconica/Switzerland | Acetaminophen 1g/100ml | IV infusion | 400 ml | UD | UD |
| M1 | Oubragyl/Syria | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 0.15±0.001 | 45 |
| M2 | Metrodar-darnista/Ukraine | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 0.13±0.003 | 39 |
| M3 | Metromark/India | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 0.1±0.005 | 30 |

*D= eye drop, P= paracetamol IV infusion, M= Metronidazole IV infusion UD=undetectable*

***Table 3: Quantitative Ni Analysis Results with Products Information and Maximum Daily Doses (ml)***

| Code | Pharmaceutical Product | Active Ingredient | Dosage form | Max. Daily Dose (ml) | Ni µg/ml (ppm) | Maximum Daily Consumed Amount of Ni µg/day |
|---|---|---|---|---|---|---|
| D1 | Apidex/jordan | Dexamethasone phosphate | Eye drop | 1ml | 0.073± 0.003 | 0.073 |
| D2 | Tobracin/jordan | Tobramycin | Eye drop | 1ml | 0.014± 0.002 | 0.014 |
| D3 | Ciprofarm/Ukraine | Ciprofloxacin | Eye drop | 1ml | 0.01±0.001 | 0.01 |
| D4 | Dexachlor/Greece | Dexamethasone/ chloramphenicol | Eye drop | 1ml | 0.02±0.003 | 0.02 |
| P1 | Dolocetam/India | Acetaminophen 1g/100ml | IV infusion | 400 ml | UD | UD |
| P2 | Feveral/Pakistan | Acetaminophen 1g/100ml | IV infusion | 400 ml | UD | UD |
| P3 | Paraconica/Switzerland | Acetaminophen 1g/100ml | IV infusion | 400 ml | UD | UD |
| M1 | Oubragyl/Syria | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 5± 0.002 | 1500 |
| M2 | Metrodar-darnista/Ukraine | Metronidazole 0.5 g/100ml | IV infusion | 300ml | UD | UD |
| M3 | Metromark/India | Metronidazole 0.5 g/100ml | IV infusion | 300ml | UD | UD |

*D= eye drop, P= paracetamol IV infusion, M= Metronidazole IV infusion, UD=undetectable*

***Table 4: Quantitative Cu analysis results with products information and maximum daily doses (ml)***

| Code | Pharmaceutical Product | Active Ingredient | Dosage form | Max. Daily Dose (ml) | Cu µg/ml (ppm) | Maximum Daily Consumed Amount of Cu µg/day |
|---|---|---|---|---|---|---|
| D1 | Apidex/jordan | Dexamethasone phosphate | Eye drop | 1ml | 0.084± 0.004 | 0.084 |
| D2 | Tobracin/jordan | Tobramycin | Eye drop | 1ml | 0.075± 0.002 | 0.075 |
| D3 | Ciprofarm/Ukraine | Ciprofloxacin | Eye drop | 1ml | UD | UD |
| D4 | Dexachlor/Greece | Dexamethasone/ chloramphenicol | Eye drop | 1ml | UD | UD |
| P1 | Dolocetam/India | Acetaminophen 1g/100ml | IV infusion | 400ml | UD | UD |
| P2 | Feveral/Pakistan | Acetaminophen 1g/100ml | IV infusion | 400ml | UD | UD |
| P3 | Paraconica/Switzerland | Acetaminophen 1g/100ml | IV infusion | 400ml | UD | UD |
| M1 | Oubragyl/Syria | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 0.12± 0.003 | 36 |
| M2 | Metrodar-darnista/Ukraine | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 0.2± 0.001 | 60 |
| M3 | Metromark/India | Metronidazole 0.5 g/100ml | IV infusion | 300ml | 0.1 ± 0.001 | 30 |

*D= eye drop, P= paracetamol IV infusion, M= Metronidazole IV infusion UD=undetectable*

## Discussion

With increasing industrial activities, urbanization, energy consumption and intensive agricultural production especially in developing countries, heavy metal pollution including air, water and soil has accelerated worldwide, posing an increasing concerns about human health and environmental sustainability (Ondrasek *et al*., 2025).

In our study, the Pb analysis in the selected pharmaceutical products (Table 2) shows that 7 samples (70%) were within the safe limits. Otherwise, the three metronidazole IV infusion samples (30%) exhibit significantly high Pb content.

According to the ICH Q3D guideline, these three samples exceeded the parenteral PDE of 5 µg/day (Ulman *et al*., 2012), with M1 reaching nine times the PDE**,** raising a significant toxicological concern, particularly for hospitalized patients requiring repeated doses and/or prolonged therapy**.**

The paracetamol IV infusion samples P1, P2 (0.01±0.003, 0.01±0.002 µg/ml) (Table 2) exhibit high Pb levels, although they are within the PDE**,** but are so close to the toxic levels.

The above analysis outcomes raise health concerns about the safety of these critical products, as Pb levels could cause CNS, cardiovascular system as well as premature death (Kinally *et al*., 2025)

The Ni analysis results (Table 3) revealed that all samples except one were within ICH Q3D safe limit (Ulman *et al*., 2012). The metronidazole IV infusion sample M1 (5±0.002 µg/ml) (Table 3) containing significantly high level of Ni with 75 times the PDE**.** These extremely high levels of Ni in this product may pose acute health problem such as allergy and increasing risk of cancer (Begum *et al*., 2022; Tramontana *et al*., 2020)**.**

The Cu analysis indicated that all ten samples were within safe limits according to the ICH Q3D guideline (Ulman *et al*., 2012) (Table 4)**.**

The detection of elevated levels of Pb and Ni in pharmaceutical formulations represents serious quality and safety concerns, as both elements are classified as toxic elemental impurities according to the ICH Q3D guideline (Ulman *et al*., 2012)**.**

The presence of these elements could originate from raw materials, lead-based pigment as well as equipment and packaging system. These low quality products could be the result of bad manufacturing circumstances, neglected equipment maintenance, along with weak quality control regulations in these manufacturers (Onyemali, 2024; Ulman *et al*., 2012).

**Conclusion**

Eye drops and parenterals are considered critical dosage forms due to their route of administration that requires high sterility and purity of the used excipient. The elevated concentrations of heavy metals in such products indicate lack in raw material and final product quality control, bad equipment maintenance and substandard manufacturing practices.

In this study, the levels of (Pb, Ni, and Cu) were investigated in ten samples, including four eye drops and six IV infusions. The results were compared with the ICH Q3D guidelines. The analysis revealed that three samples contained high levels of Pb, and one sample contained high levels of Ni. the presence of these metals raise a significant safety concerns, particularly for patients requiring prolonged therapy.

The analysis of these samples revealed the wide distribution of such contaminated products that could be harmful to large number of people, our suggestion is to support further screening studies in this field to confirm these findings, including additional products and various heavy metals to be investigated. Health authorities and quality control personnel should be aware of these contaminants by conducting accurate and accessible heavy metal testing as part of quality control requirements, as well as withdrawing contaminated products from the market and applying appropriate sanctions on manufacturers and suppliers.

**Conflict of Interest**

The author(s) declare that there is no conflict of interest regarding the publication of this article.

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