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# Determination of Inorganic Metal Ions in Marketed Drugs Formulation via Flame Photometry

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## Abstract

**Introduction:** Inorganic metal ions such as sodium, potassium, and calcium are crucial for the proper functioning of the human body. Various spectroscopic techniques have been employed for the quantitative and qualitative determination of these mineral ions, with flame emission spectroscopy being widely used for detecting metal ions like sodium, potassium, calcium, and lithium. Flame emission photometry is commonly applied to biological samples for estimating sodium, potassium, and calcium levels. This method has also been used to detect metal ions in wastewater, gasoline, cement, and blood. **Methods:** In the current study, the flame photometric technique has been utilized for the quantitative analysis of different inorganic metal ions (Sodium, Potassium, and Calcium) in various pharmaceutical drug formulations. The flame photometric technique has been calibrated with these metal ion standard solutions. This calibrated technique has employed for calculating the concentration (mg) of these metal ions in different pharmaceutical drugs formulations and compared with the marketed concentration (mg). This technique is found to be very reliable for sodium metal ion-based drugs such as Epival (light green), Benzyl penicillin sodium (violet), Diclofenac sodium (cyan) etc, while the calculated amounts of potassium and calcium were lower than the reported values in potassium-based drugs such as DV-Losartan (dark blue), UROCIT-K (yellow), Diclofenac potassium (violet), etc and .calcium-based drugs such as Calcium gluconate injection (light green), Caltrix, Caldree (dark blue), Calcium -P (violet) etc. Similarly, this method is validated with linearity and goodness of fit values of sodium, potassium, and calcium based drugs, such as sodium=0.999x-0.641, R2=0.994, potassium: y=0.943x+3.753, R2=0.995, and calcium: y=0.766x+20.279, R2=0.924, respectively. The proposed technique is well validated and can be employed for the estimation of other inorganic metal ions. **Results:** This study utilized the flame photometric technique to quantify inorganic metal ions, sodium, potassium, and calcium in various pharmaceutical formulations. The concentrations of the ions (mg) in different pharmaceutical drug samples were determined and compared with their labeled marketed values. The findings highlight the accuracy and reliability of flame photometry in assessing metal ion content in pharmaceutical products.

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## Introduction

Humans are exposed to various metal ions through diet, environmental factors, and occupational settings. Some metal ions are essential for biological functions, while others can be toxic and pose health risks depending on the dose and duration of exposure. Minerals required by the human body in larger quantities are known as macro minerals, while those needed in smaller amounts are called trace minerals (Mertz, 1981). The seven essential macro minerals are sodium, potassium, calcium, phosphorus, magnesium, sulfur, and chloride. Trace minerals, which are also essential, include iron, zinc, cobalt, and manganese (Fernandes et al., 1997; Itaya et al., 1996; Nielsen et al., 2008). The deficiency or absence of essential metals can impair vital functions of the human body. Some trace minerals, such as $Sr^{2+}$, are not essential but can be beneficial, such as in treating osteoporosis. Similarly, trace minerals like lithium and rubidium are used in the treatment of bipolar disorders (Cipriani et al., 2013). The human body requires less than 2.3 grams of sodium daily. Higher doses can lead to high blood pressure and potentially heart diseases. Individuals consuming alcohol are at a higher risk of blood pressure issues when ingesting sodium (Pohl et al., 2013; Raposo et al., 2015). Biologically, sodium is crucial for maintaining body fluids through osmoregulation and for the proper functioning of nerve cells (Denton et al., 1996; Noda & Matsuda, 2022). Additionally, sodium plays a role in enzyme activity (Page & Di Cera, 2006; Vašák & Schnabl, 2016). Hyponatremia is caused by low sodium levels in the plasma (Adrogué & Madias, 2000; Goh, 2004). It leads to kidney dysfunction and disturbances in osmotic balance. Symptoms of sodium deficiency include low blood pressure, muscle cramps, and dehydration. In hyponatremia, serum sodium levels are less than 135 mmol/L (Lockett et al., 2019).

Potassium is essential for vital bodily functions, maintaining blood levels between 3.5-5.0 mmol/L. The sodium-potassium ATPase pump regulates its plasma content, crucial for nerve signaling and muscle contraction. The body needs 50-150 mmol of potassium daily. Potassium also helps prevent high blood pressure, with hypertensive patients recommended to intake 3500-5000 mg daily (Goel, 2016; Udensi & Tchounwou, 2017). Hypokalemia refers to a low level of potassium in plasma, an electrolyte imbalance in the human body (Kardalas et al., 2018; Unwin et al., 2011). Treatment typically involves oral or intravenous potassium supplementation. Potassium citrate is effective in treating kidney stones. Management of hypokalemia often includes potassium tablets or intravenous administration (Kardalas et al., 2018).

Calcium, a vital mineral constituting approximately 1 kg of body weight, requires adults to consume 700-800 mg daily (Lambert et al., 2017). Normal serum calcium levels range from 2.10 to 2.60 mmol/L, with Vitamin D essential for its proper utilization (Cooper & Gittoes, 2008). Found predominantly in bones and teeth, calcium contributes to their strength via hydroxyapatite. Essential as a cofactor for many enzymes, calcium deficiency can prompt bone calcium mobilization, driven by increased parathyroid hormone levels (Toyoshima et al., 2000). Calcium deficiency can lead to several health issues. Insufficient calcium intake may weaken bones, increasing the risk of osteoporosis and fractures (Chiodini & Bolland, 2018; Heaney, 1992). It can also impair tooth strength and lead to dental problems. Muscle cramps, spasms, and numbness are common symptoms, as calcium is essential for proper nerve function (Miller & Layzer, 2005). Furthermore, inadequate calcium levels can affect heart health and increase the risk of hypertension (Cormick & Belizán, 2019; Li et al., 2018).

Atomic spectroscopy, the oldest method for determining the presence of metals, relies on the radiation emitted by flames, which is characteristic of the elements present. Advances in instrumentation have significantly expanded the application of atomic spectroscopy across various fields. Photoelectric flame photometry, a branch of atomic spectroscopy, is employed in inorganic chemical analysis to measure the concentration of specific metal ions like sodium, potassium, lithium, calcium, and cesium (Bhupathyraaj et al., 2024; Brown & Milton, 2005; Dean et al., 1997; Gandhi et al., 2022; Haneef & Ghosh; Herlinawati et al.;

Kamble et al., 2021; L'vov, 1997; Mizutani, 2023; Torres-Herrera et al., 2022; Wiyantoko et al., 2021). In flame photometry, these metal ions are analyzed when they are present in atomic form within the spectrum. Huang et al. (2009) utilized hydrophilic interaction liquid chromatography (HILIC) to analyze inorganic counter ions such as sodium, chloride, bromide, magnesium, sulfates, potassium, and phosphates in pharmaceutical formulations. Their method employed a polymer-based stationary phase and a mobile phase comprising 0.1M ammonium formate and ammonium acetate, with a flow rate set at 1.0 mL/min (Huang et al., 2009). The study compared this approach with ion chromatography for assessing counter ions in pharmaceutical products. Barros *et al.* (2012) analyzed sodium and potassium in biodiesel by flame atomic emission spectroscopy (Barros et al., 2012). Chaves *et al.* (2008) analyzed sodium and potassium in different vegetable oils (Chaves et al., 2008). Raposo et al. (2015) conducted an analysis of sodium, potassium, and calcium in biodiesel using flame emission spectroscopy with a continuous electromagnetic detector (Raposo et al., 2015). Although advanced techniques such as inductively coupled plasma mass spectrometry (ICP-MS), atomic absorption spectroscopy, and ICP-based atomic emission methods offer higher sensitivity and multi-element capability, they typically require expensive instrumentation, specialized facilities, and extensive maintenance, which may limit their routine use in many quality control settings. For example, comparative studies have shown that ICP-based methods can determine multiple metals simultaneously with high precision, but they are generally more resource-intensive than simpler techniques. In contrast, the flame photometry method used in this study provides a cost-effective, rapid, and reliable approach for the quantitative determination of alkali (sodium, potassium) and alkaline earth (calcium) metal ions at the concentration levels relevant for pharmaceutical formulations. Flame photometry has been widely applied for these analytes due to its simplicity and adequate analytical performance for routine purposes (Raposo et al., 2015).

In this research, different metal ions calcium, sodium, and potassium from various commercial tablet and powder formulations were quantified using the flame photometric technique. Critically reviewed literature said that there is no such as study publish yet. The technique was validated according to ICH guidelines and the results were compared with the label claims on the packaging of these formulations.

## Materials and methods

### *Materials*

Calcium chloride ($CaCl_2$) primary standard, Distilled water, Sodium Chloride (NaCl) primary standard, Potassium chloride (KCl) primary standard.

### *Method*

*Formulation Samples*

Commercial samples of Drug products containing Calcium (Calcium gluconate injection, ABO-CAL, Caltrix, Calcium –P, Caldree, and Cal-Dee), Sodium (Citralka, Diclofenac sodium, Naproxen sodium, Epival, Benzyl penicillin sodium, and Norsaline) and Potassium (Diclofenac potassium, DV-Losartan, UROCIT-K, NEO-K, and MOM-VIT). Few different formulations were randomly evaluated during the course of this study in order to check the validity of this developed method.

*Estimation of Metal ions in Pharmaceutical Dosages*

The methodology for the estimation of Calcium, Sodium and Potassium metal ions in pharmaceutical preparations includes the following steps.

*Standard Sample Preparation*

To prepare the standard stock solutions, 1000 ppm solutions were made for each metal ion using their corresponding salts: calcium chloride ($CaCl_2$) for calcium, sodium chloride (NaCl) for sodium, and potassium chloride (KCl) for potassium. The salts were weighed accurately and dissolved in deionized water to achieve a final concentration of 1000 ppm for each metal ion. From these 1000 ppm stock solutions, a series of diluted working solutions with concentrations ranging from 10 ppm to 50 ppm were prepared by serial dilution with deionized water. These working solutions were then used for the calibration process. During calibration, the flame photometer instrument measured the signal (intensity or response) for each of the prepared working solutions to generate the calibration data. A calibration curve was plotted by correlating the instrument's response with the known concentrations of the working solutions. This calibration curve was later used to determine the concentrations of unknown samples by interpolating their signals on the curve.

*Sample Analysis*

Similarly, stock solutions of sodium, potassium, and calcium containing drugs were prepared (100 ppm), and from these stock solutions, we prepared different concentration solutions (0-50 ppm). These different concentration solutions (0-50 ppm) were analyzed using flame photometry (Sherwood 410 classic flame photometer). After that, compare the concentration (mg) of metal ions obtained from this method with that of the commercially available concentration (mg).

*Method Validation*

The proposed method was validated according to standard analytical guidelines to ensure its reliability for quantitative determination of sodium, potassium, and calcium in pharmaceutical formulations. The validation parameters included linearity, accuracy, and precision.

*Linearity*

Calibration curves were constructed by plotting the measured concentrations against the reported amounts of each drug. The regression equations and correlation coefficients ($R^2$) were as follows:

- **Sodium:** $y=0.999x-0.641$, $R^2=0.994$
- **Potassium:** $y=0.943x+3.753$, $R^2=0.995$
- **Calcium:** $y=0.766x+20.279$, $R^2=0.924$

These results demonstrate strong linearity and good agreement between measured and reported values over the tested concentration ranges.

*Accuracy*

Accuracy was assessed by comparing the experimentally determined concentrations with the labeled (claimed) amounts of the marketed drugs. The results indicated that the method could reliably determine drug content within acceptable limits.

*Precision*

Intra-day and inter-day precision studies were performed, and the relative standard deviation (RSD) values were found to be within acceptable ranges, indicating high repeatability and reproducibility of the method.

## Results and discussion

Flame photometry technique were used to estimate the concentrations of different metal ions (Calcium, Sodium, and Potassium) in commercial available drugs formulations via standard calibration method. The estimated concentration of each metal ion in different formulations are show below along with its standard concentration calibration graph.

***Estimation of Sodium Ion in pharmaceutical formulations***

The flame photometer was calibrated with sodium standard solution between concentration (10-50ppm) and straight line was obtained as shown in **Fig. 1.**

Then this calibrated method was used for calculating the concentration of sodium ion in different commercially available drug formulations like Epival (light green), Benzyl penicillin sodium (violet), Diclofenac sodium (cyan), etc., as shown in **Fig. 2.** The calculated concentration of these drug formulations is compared with the market concentration as presented in **Table 1**. However, the PPM concentration of these drugs is converted to grams and milligrams to compare with the marketed concentrations, as shown in **Table 2,** and the conversions of PPM to g/mg were presented in supplementary material as **Fig. S1-S4**. Tables 1 and 2 provide a detailed comparison between the experimental concentrations obtained for sodium-based drug formulations and their corresponding marketed concentrations. The data highlights the agreement or variation between the two sets of concentrations, ensuring accuracy and reliability. All measurements are presented in appropriate units, such as grams (g) or milligrams (mg), for clarity and consistency in interpretation.

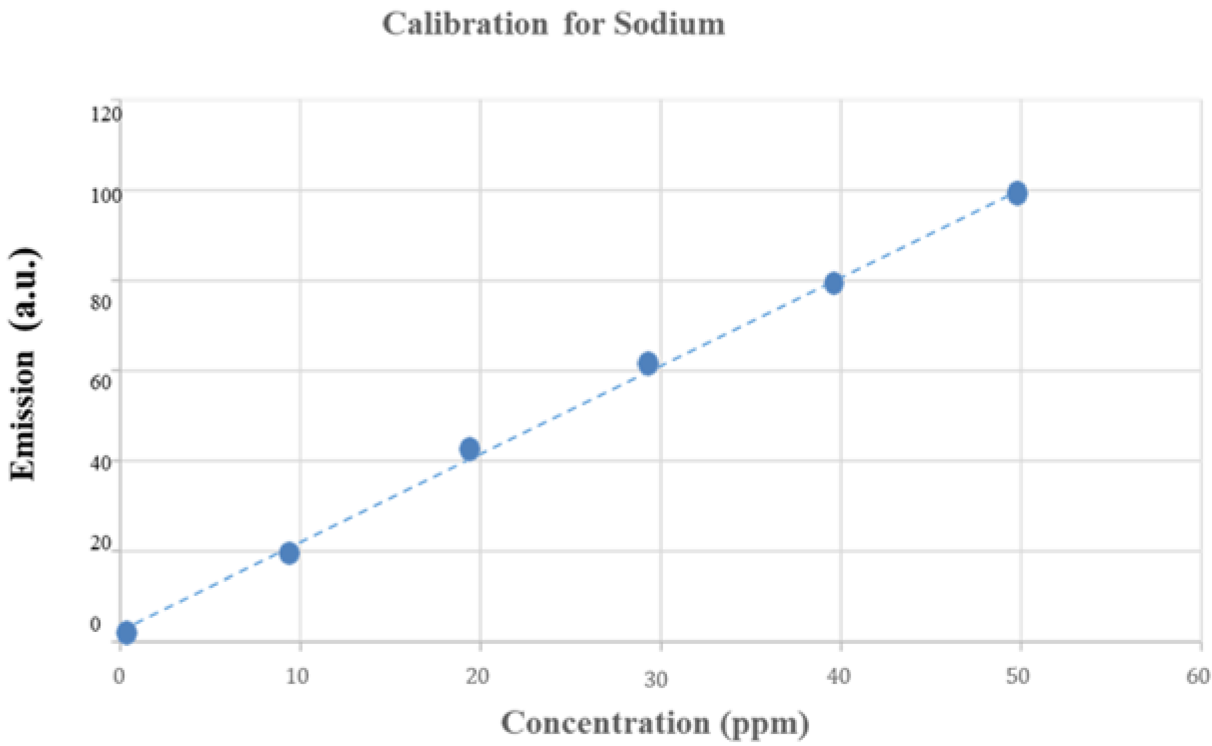


**Fig. 1:** Calibration graph of Sodium standard solution.

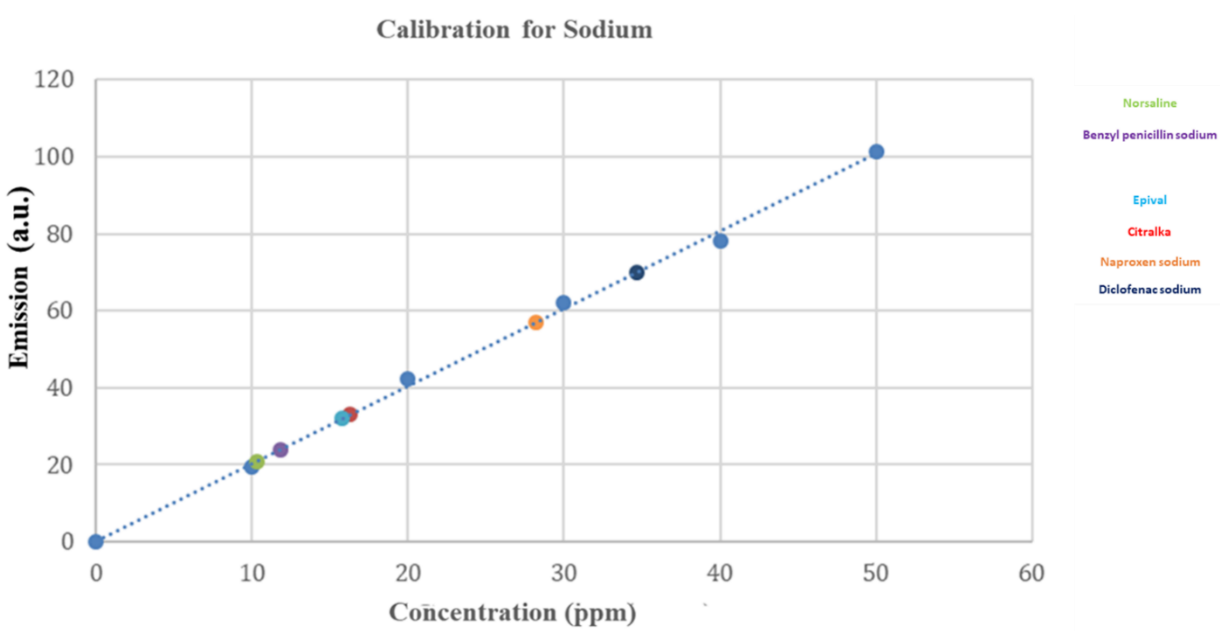


**Fig. 2**: Estimated concentrations of Sodium ions in different drug formulations.

Table 1: Pharmaceutical formulations of Sodium with their respective emission and concentration

| Sr. # | Drug samples | Emission (a.u.) | Concentrations of drugs (ppm) |
|---|---|---|---|
| 1 | Citralka | 33 | 16.196 |
| 2 | Norsaline | 21 | 10.203 |
| 3 | Benzyl penicillin sodium | 24 | 11.701 |
| 4 | Epival | 32 | 15.574 |
| 5 | Naproxen sodium | 57 | 28.151 |
| 6 | Diclofenac sodium | 70 | 34.276 |

**Table 2**: The calculated concentration of Sodium ion-containing drug formulations is compared with the marketed drugs.

| Drug name | Reported amount of sodium | The calculated amount of sodium |
|---|---|---|
| Citralka | 0.238mg | 0.321mg |
| Norsaline | 3.53mg | 4mg |
| Benzyl penicillin sodium | 41.18mg | 39.33mg |
| Epival | 18.5mg | 15mg |
| Naproxen sodium | 54.93mg | 56mg |
| Diclofenac sodium | 3.61mg | 3.42mg |

***Estimation of Potassium Ion in pharmaceutical formulations***

The flame photometer was calibrated with Potassium standard between concentration (10-50ppm) and straight line was obtained as shown in **Fig. 3**.

However, a calibrated method was used for calculating the concentration of potassium ion in different commercially available drug formulations like DV-Losartan (dark blue), UROCIT-K (yellow), Diclofenac potassium (violet), etc as shown in **Fig. 4**. The calculated concentration (ppm) of these drug formulations is compared with the market concentration (ppm) as presented in **Table 3**. However, the PPM concentration of these drugs is converted to grams and milligrams to compare with the marketed concentrations, as shown in **Table 4,** and the conversions of PPM to g/mg were presented in supplementary material as **Fig. S5**. Tables 3 and 4 present a comprehensive comparison of the experimental concentrations of potassium-based drug formulations with their corresponding marketed concentrations. The data emphasizes the level of agreement or discrepancies between the two sets of values, ensuring a focus on accuracy and reliability. All concentrations are reported in appropriate units, such as grams (g) or milligrams (mg), to maintain clarity and consistency in the analysis.

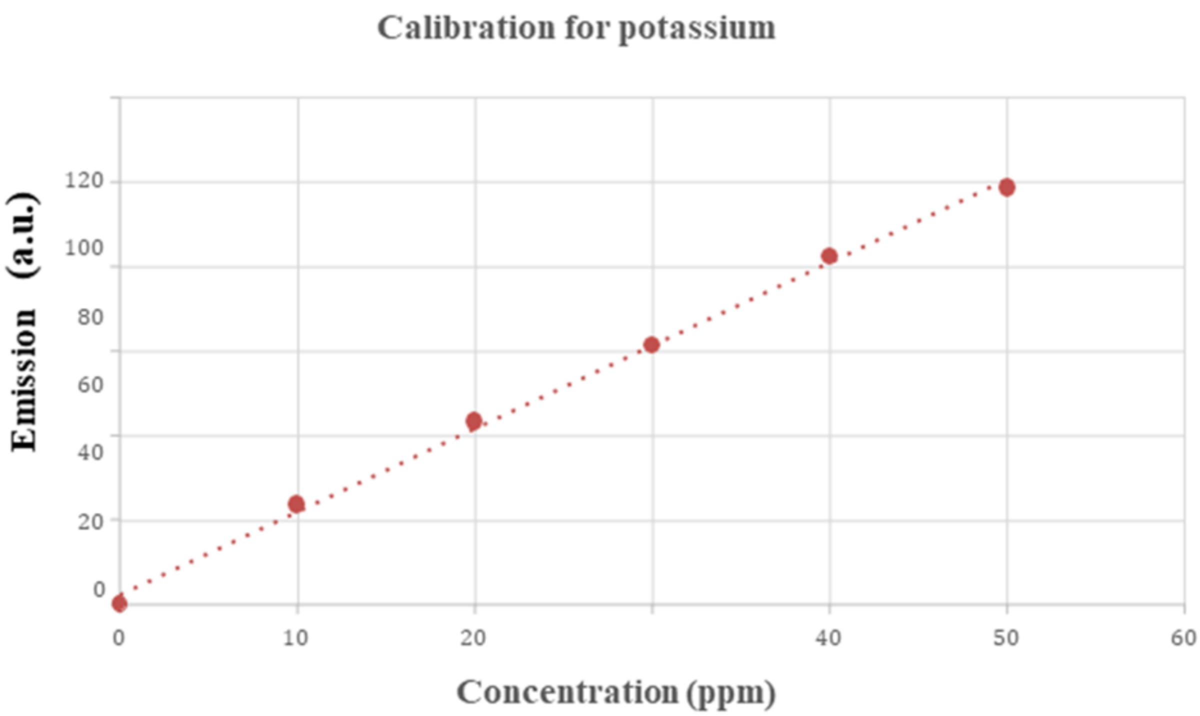


**Fig. 3**: Calibration graph of Potassium standard solution.

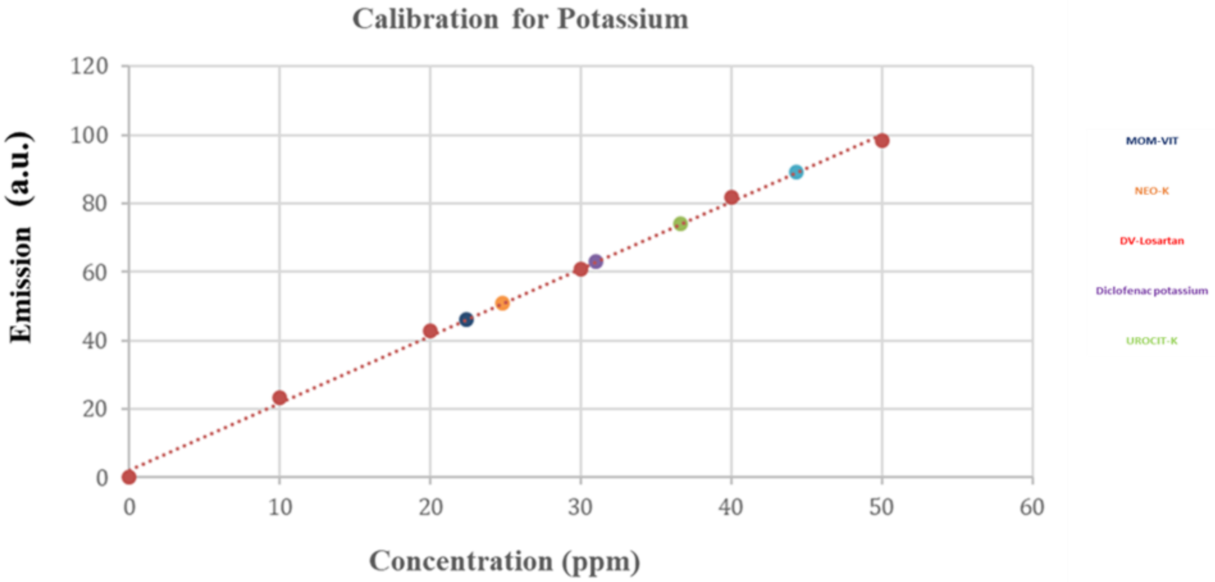


**Fig. 4**: Estimated concentrations of Potassium ion in different drug formulations.

**Table 3**: Pharmaceutical formulations of Potassium with their respective emission and concentration

| Sr. # | Drug samples | Emission (a.u.) | Concentration(ppm) |
|---|---|---|---|
| 1 | Diclofenac potassium | 74 | 36.18 |
| 2 | DV-Losartan | 63 | 30.93 |
| 3 | UROCIT-K | 89.1 | 44.60 |
| 4 | NEO-K | 50.8 | 24.33 |
| 5 | MOM-VIT | 46.1 | 21.85 |

**Table 4**: The calculated concentration of Potassium ion containing drugs formulation are compared with the marketed drugs concentration.

| Drug name | Reported amount of potassium | Calculated amount of potassium |
|---|---|---|
| Diclofenac potassium | 5.8mg | 5.6mg |
| DV-Losartan | 4.2mg | 3.09mg |
| UROCIT-K | 446mg | 412mg |
| NEO-K | 249.4mg | 261.7mg |
| MOM-VIT | 10mg | 11.32mg |

***Estimation of Calcium Ion in pharmaceutical formulations***

The flame photometer was calibrated with calcium standard between concentrations (10-50ppm), and a straight line was obtained as shown in **Fig. 5.**

After that this calibrated method was used for calculating the concertation of calcium ion in different commercially available drugs formulation like Calcium gluconate injection (light green), Caltrix, Caldree (dark blue), Calcium -P (violet) etc as shown in **Fig. 6.** The calculated concentration (ppm) of these drugs formulation were compared with that of commercially available drugs concentration (ppm) as presented in **Table 5**. Furthermore, the concentrations (ppm) of these drugs are converted to grams and milligrams to compare with the commercially available drugs' concentrations (g/mg), as shown in Table 6, and the conversions of PPM to g/mg are presented in the supplementary material as **Fig. S6-7**. Tables 5 and 6 provide a detailed comparison between the experimental concentrations obtained for calcium-based drug formulations and their corresponding marketed concentrations. The data highlights the agreement or variation between the two sets of concentrations, ensuring accuracy and reliability. All measurements are presented in appropriate units, such as grams (g) or milligrams (mg), for clarity and consistency in interpretation.

However, these Flame Photometric results show that our developed method is very reliable for Sodium and Potassium metal ions. However, less reliable for supplements, the calculated amounts of potassium and calcium were lower than the reported values. Flame photometry offers a convenient way to determine concentrations at ppm levels for Calcium ions in different pharmaceutical drug formulations. These pharmaceutical drug formulations are very frequently used in our daily lives. This validated method can be applied for calculating the concentration of other metal ions in different foods and other samples to check their quality and quantity.

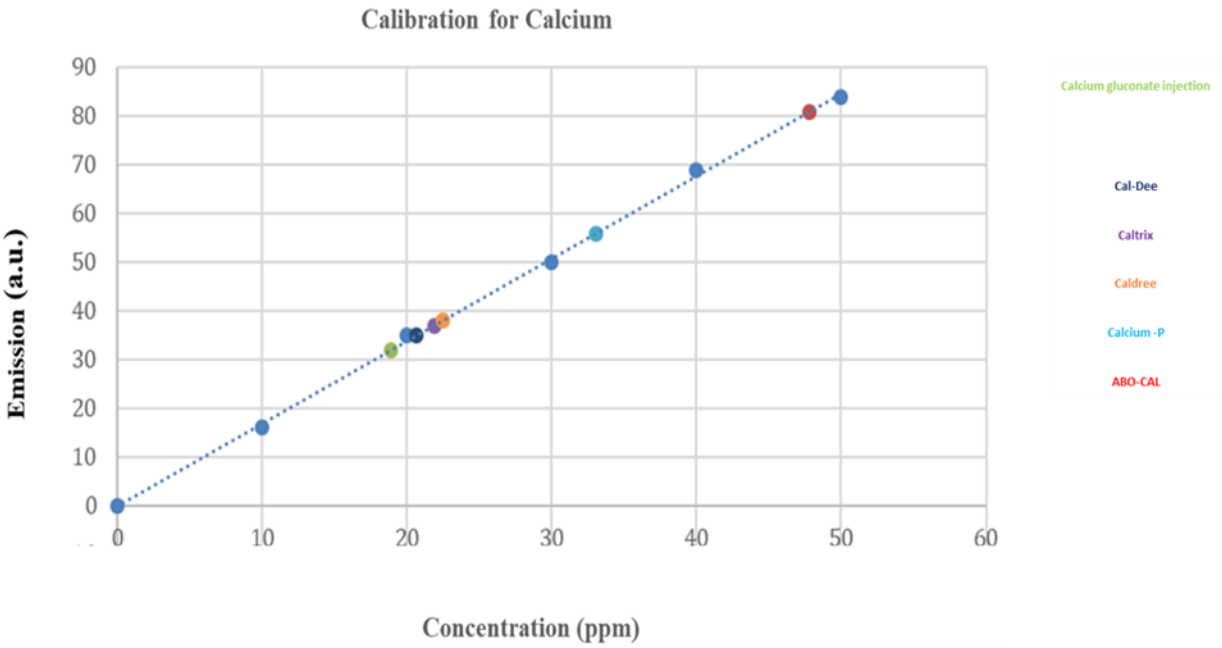


**Fig. 6:** Estimated concentrations of Calcium ion in different drugs formulations.

**Table 5:** Pharmaceutical formulations of Calcium with their respective emission and concentration.

| Sr. # | Drug name | Emission (a.u.) | Concentration(ppm) |
|---|---|---|---|
| 1 | ABO-CAL | 81 | 47.73 |
| 2 | Calcium gluconate injection | 32 | 18.95 |
| 3 | Caltrix | 37 | 21.89 |
| 4 | Calcium -P | 56 | 33.05 |
| 5 | Caldree | 38 | 22.48 |
| 6 | Cal-Dee | 35 | 20.72 |

**Table 6:** The calculated concentration of Calcium ion-containing drug formulations is compared with the marketed drugs.

| Drug name | Reported amount of Calcium | Calculated amount of Calcium |
|---|---|---|
| ABO-CAL | 268mg | 238mg |
| Calcium gluconate injection | 88.29mg | 94mg |
| Caltrix | 300mg | 216mg |
| Calcium -P | 81.24mg | 66mg |
| Caldree | 240mg | 220mg |
| Cal-Dee | 240mg | 220mg |

## Conclusion

The innovation in this work lies in the development of a cost-effective and accessible flame spectrometry technique that does not require expensive equipment, making it suitable for routine use in various laboratory settings. This method is both simple to implement and highly precise, offering a straightforward approach to estimating inorganic metal ions in pharmaceutical preparations. By utilizing basic mathematical calculations, the technique allows for the efficient determination of concentrations at the ppm level. Furthermore, it demonstrates versatility by effectively analyzing multiple inorganic metal ions, such as sodium, potassium, and calcium, and has the potential for adapting to the analysis of other metal ions as well. The method's validation ensures its reliability, making it a valuable tool for pharmaceutical quality control and further research applications. To the best of my knowledge, this is the first study to employ such a technique for analyzing metal ions in the specific drug formulations tested, which distinguishes it from previous research. These innovative aspects highlight the potential of this flame photometry technique to provide an affordable, easy-to-use, and reliable solution for the analysis of metal ions in commercial medicines and laboratory-prepared pharmaceutical formulations.

## Highlights

1. Flame photometric technique utilized for the quantification analysis of different inorganic metal ions (Sodium, Potassium and Calcium).
2. Different pharmaceutical drug formulations.
3. This technique is reliable for Sodium metal ion and for supplements, the calculated amounts of potassium and calcium were lower than the reported values.

## Authors contributions

Conceptualization, Maira Afzal.; methodology, Hamid Ali; software, Abdur Rehman; validation, Maira Afzal; formal analysis, Khalil Ur Rehman; investigation, Umar Farooq; resources, Maira Afzal; data curation, Maira Afzal; writing-original draft preparation, Maira Afzal; writing-review and editing, Maira Afzal; visualization, Maira Afzal; supervision, Muhammad Abu Bakar. All authors have read and agreed to the published version of the manuscript.

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## Conflict of interest

There is no conflict of interest.

## Declaration of generative AI and AI-assisted technologies in the writing process

The author declares that artificial intelligence tools were used in the preparation of this manuscript for language editing and clarity purposes only. The AI tools did not generate original research content, data, analyses, or conclusions. All scientific interpretations, results, and final decisions remain the responsibility of the author.

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