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Spectrophotometric Quality Assessment of Various Brands of Iron-Containing Drugs Sold in Ado-Ekiti, Nigeria

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ABSTRACT

Background: Iron is a crucial component for sustaining life in living beings and plays a key role in the treatment of anaemia. This study evaluated the iron (II) content in different brands of iron-containing drugs commercially available in Ado-Ekiti, Nigeria.

Methods: 15 pharmaceutical products, comprising tablets, capsules, and syrups, were procured from licensed pharmacies in Ado-Ekiti. Iron content was quantified by UV–visible spectrophotometry. Initially, ferrous ions (Fe^{2+}) in the samples were reacted with 1,10-phenanthroline under acidic conditions to form an orange-red chelate exhibiting a maximum absorbance at 508 nm**.** Iron concentrations were then interpolated from a constructed standard Fe^{2+} calibration curve and compared with the British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) assay limits for the iron salts.

Results: Among the 15 samples analysed, syrups had the highest frequency, with 73.33% of the entire sample manufactured locally. In the assay test, 9 brands (2 tablets, 5 capsules, and 2 syrups), which constituted 60% of the samples, were found to have Fe^{2+} levels within the BP and USP limits. However, 40% of the analysed samples had iron content that fell outside the acceptable limits specified in the pharmacopoeias.

Conclusion: The study's findings revealed discrepancies between the actual Fe^{2+} content and the claimed values across the various tested brands. This raises a significant issue about the quality of some iron-containing drugs sold in Ado Ekiti and Nigeria generally, highlighting the need for stringent regulation and monitoring of drugs by relevant regulatory authorities.

Keywords: Iron, spectrophotometry, anaemia, ferrous sulphate, 1,10-phenanthroline.

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INTRODUCTION

Iron has become an essential element and electrolyte necessary for human life, playing a key role in metabolic processes such as delivering oxygen to various cells and tissues within the body.[1] Haemoglobin, a vital component of red blood cells, makes up 60 to 70% of the body's iron,[2] while the rest is converted into ferritin and hemosiderin, stored in the liver, spleen, bone marrow, duodenum, and skeletal muscle.[3] Due to iron's importance in many physiological and cellular functions, low levels can lead to various health problems. Healthcare professionals worldwide face a complex challenge in managing iron deficiency, especially among vulnerable groups such as pregnant women, children, and cancer patients.[4] Anaemia, caused by a low red blood cell count, presents serious global health issues, affecting 40% of children under five, 37% of pregnant women, and 30% of women of reproductive age.[5] According to the Institutes of Health (2023),[6] the Recommended Dietary Allowance (RDA) for iron intake is 8 mg per day for men and postmenopausal women, 18 mg for premenopausal women, 9–10 mg for breastfeeding women, 27 mg daily for pregnant women, and 15 mg for adolescent girls (14–18 years). Iron is mainly obtained from dietary sources and nutritional supplements. However, when the body finds it difficult to absorb iron from food, iron-deficiency anaemia can develop,[7] which necessitates the use of oral iron medications. These are generally the first-line treatment for anaemia and are often prescribed or available over the counter (OTC).

Iron-based products can be classified as either dietary supplements or medications and are accessible globally in pharmacies and hospitals. They come in a variety of forms, such as tablets, caplets, soft and hard gelatin capsules, oral drops, and intravenous injection solutions.[8] These formulations vary in their iron content, which may be combined with other active ingredients like folic acid, vitamins, and minerals in different chemical salt forms, including sulphate, gluconate, fumarate, ammonium citrate, and glycinate. Additional types of iron salts include ferrous glycine carbonate, tartrate, iodide, chloride, sodium citrate, aspartate, and succinate.[9] Excessive iron intake can be harmful to infants and young children, resulting in negative consequences such as impaired growth, increased vulnerability to illnesses, and developmental delays, while in adults, it can adversely affect the liver, brain, and heart, potentially resulting in serious conditions like heart attacks or strokes.[10,11] Therefore, adhering to the recommended dosage of iron is essential. It is crucial to evaluate these iron supplements to ensure their iron content agrees with the claims made by manufacturers. Several investigations have shown that the actual contents of many dietary supplements available in the market, when subjected to various analytical assays, often do not meet the claimed amounts indicated on their labels.[12] Products that do not meet established quality criteria are classified as substandard or counterfeit and can lead to risks of negative health effects and treatment failures.[13] Counterfeit medications contain inaccurate amounts of the active pharmaceutical ingredient (API) or dangerous impurities that are packaged in a way that closely resembles the genuine product, making it difficult to distinguish between the two unless chemical analysis and detection tests are conducted on them.[14]

Various analytical methods, such as titrimetry, UV-visible spectrophotometry, atomic absorption spectrophotometry, fluorimetry, and chromatographic techniques, have been utilised to assess the iron content in different supplements and pharmaceutical products.[15] Among these methods, UV-visible spectrophotometry is particularly noted for its rapidity, selectivity, cost-effectiveness, and adaptability. Consequently, it is deemed a practical substitute for the more complex and pricier techniques commonly employed in pharmaceutical analysis. UV-visible spectrophotometric technique for quantitation of Fe^{2+} in drug samples is based on the formation of coloured complexes between Fe^{2+} and 1,10-phenanthroline, which absorbs at a peak wavelength of 508 nm.[16] In other analytical techniques like titrimetry, iron determination (as Fe^{2+}) through redox titration is based on iron's capacity to reduce potent oxidizing agents like ammonium cerium(IV) sulphate and potassium permanganate (VII) $KMnO_4$ into Ce^{3+} and Mn^{2+}, respectively, leading to the oxidation of iron from Fe^{2+} to Fe^{3+}, which is highlighted by a distinct colour change at the endpoint of the reaction.[17] This research intends to assess the quality of various iron-containing pharmaceuticals in Ado-Ekiti, a city in Southwest Nigeria. The outcomes of this investigation will undoubtedly provide valuable insights for the effective decision-making process by health regulatory authorities and stakeholders within the healthcare field. Although multiple techniques are available for iron analysis, this research opted for UV-

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visible spectrophotometry to quantitatively determine the iron content in the various drug samples.

METHODOLOGY

Chemicals and reagents: Ferrous ammonium sulphate (Molychem, India) was used for the preparation of standard iron solutions. Also, 0.25% 1,10-phenanthroline (Molychem, India), 0.10 M sodium citrate (GHTech, China), 1% Hydroquinone (Merck Schuchardt OHG, Germany), and 6 M Hydrochloric acid (JHD, China) solutions were prepared by taking a suitable amount of respective reagents in distilled water. All chemicals are of analytical grade and were purchased locally.

***Instrumentation*:** A Mettler Toledo weighing balance (ME204E, Switzerland) was used to weigh the samples accurately. A hotplate magnetic stirrer (BS-2H, Biobase, China) was employed to stir and heat the samples during sample digestion for UV-visible spectrophotometry. The pH of the sample and standard solutions was measured using a pH meter (PHS-25CW, Biobase, China). A biobase UV-visible spectrophotometer (BK-D560, China) was used to measure the absorbance of standard and sample solutions for the determination of iron content.

Study Area: Ado-Ekiti is located in Ekiti State in the Southwestern region of Nigeria, positioned between longitudes 5° 13' 17.0004" east of the Greenwich Meridian and latitudes 7° 37' 15.9996" north of the Equator (Figure 1). According to the National Population Commission (2006),[18] Ado-Ekiti's population is estimated to be 308,621, based on the census conducted in 2006. The state covers an area of 5,434 square kilometres and is divided into 16 local government areas across three senatorial districts, with an annual population growth rate of 3.1%. The increasing population and urbanisation of Ado-Ekiti make the city suitable for this research due to the heightened demand for enhanced access to quality healthcare services, especially pharmaceuticals.

Sample collection: Simple random sampling was used for the sample collection. Fifteen (15) different samples of iron-containing drugs were purchased from various registered pharmacies in Ado-Ekiti, Nigeria. To maintain brand identity, the samples were coded and analysed before their expiration dates. The labelled information of the drugs is presented in Table 1.

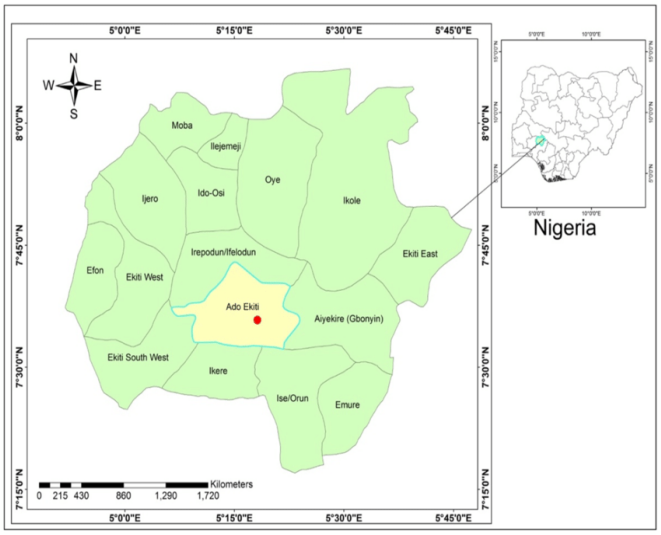

Figure 1.Map of Nigeria showing the study area

***Standard solutions preparation and construction of a calibration curve*:** Standard Fe (40 ppm) solution was prepared by dissolving 0.281 g of ammonium iron (II)sulphate hexahydrate $(NH_4)_2Fe(SO_4)_2.6H_2O$) with distilled water in a beaker, transferred to a 1 L volumetric flask, and made up to the mark with more distilled water. From the standard Fe solution (40 ppm), 10 mL was pipetted into a beaker, and the pH was determined and adjusted to ≈3.5 with sodium citrate (0.1 M) solution. Standard Fe solutions with concentrations 1, 2, 3, 4, 5, and 6 ppm were prepared by serial dilution, and their pH was adjusted to 3.5 with sodium citrate solution. Thereafter, to each of the standard solutions, 2.00 mL of 1% hydroquinone, 3.00 mL of 0.25% 1,10-phenanthroline solution were added, and the solutions were diluted to mark with distilled water and kept for 10 min before their absorbance was measured at 508 nm wavelength against a blank containing all of the reagents except the iron solution. A standard Fe calibration curve was plotted as absorbance versus concentration of Fe (ppm), which was used to determine the iron (Fe) content in the various drug samples.[19]

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Table 1: Labelled details of the different brands of iron-containing drugs marketed in Ado Ekiti

Sample Code	Dosage Form	Active ingredient (Iron Salt)	Manufacture Date (Month/Year)	Expiry Date (Month/Year)	Batch Number	NAFDAC Number	Country of Origin
S1	Tablet	Ferrous sulphate	10/2023	09/2026	23X01402	A11-100168	Nigeria
S2	Tablet	Ferrous sulphate	07/2024	06/2027	17664181	A11-100593	Nigeria
S3	Tablet	Ferrous sulphate	05/2024	04/2027	190524	04-0476	Nigeria
S4	Tablet	Ferrous sulphate	02/2024	02/2026		04-9611	Nigeria
S5	Capsule	Ferrous fumarate	02/2023	02/2026	036p2303x	04-1405	India
S6	Capsule	Ferrous fumarate	11/2023	08/2026	CC018C	04-0944	Nigeria
S7	Capsule	Ferrous fumarate	02/2024	01/2027	G240013	A4-3667	Nigeria
S8	Capsule	Ferrous fumarate	01/2023	12/2024	DFE0480A	04-0869	India
S9	Capsule	Ferrous fumarate	06/2022	06/2025	(10)023A2209X	A7-4001	India
S10	Syrup	Ferrous ammonium citrate	11/2022	10/2024	21111	04-0847	Nigeria
S11	Syrup	Ferric ammonium citrate	12/2023	11/2025	A0294	04-5740	Nigeria
S12	Syrup	Ferrous gluconate	01/2024	12/2025	4006T	04-2037	Nigeria
S13	Syrup	Ferrous gluconate	01/2024	12/2026	BT003D	04-0942	Nigeria
S14	Syrup	Ferrous ammonium citrate	11/2023	10/2025	21123	04-1194	Nigeria
S15	Syrup	Ferric ammonium citrate	01/2024	12/2026	AD34380	04-0511	Nigeria

***Sample determination by UV-visible spectrophotometry*:** Five tablets (capsules or 5 mL of syrup) randomly taken from each brand were weighed individually, and an amount equivalent to the average weight of the tablets was placed in a beaker. The sample was digested by adding 25 mL HCl (6 M) with gentle boiling (in a fume hood) for 15 minutes. The digested sample solution was completely filtered into a 100 mL volumetric flask, cooled and made to the mark with distilled water. From this stock, a 5.00 mL aliquot was transferred to another 100.0 mL volumetric flask and made up to volume with distilled water. Furthermore, a 10 mL aliquot was taken from this step and transferred into a 100 mL volumetric flask. The pH was determined and adjusted to 3.5 using sodium citrate buffer solution before making the solution to volume with distilled

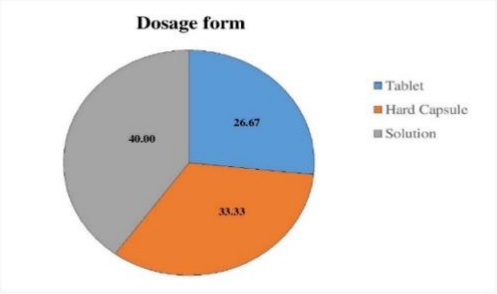

Figure 2. Distribution of the drug samples by dosage form

To each sample solution, 2.00 mL of 1% hydroquinone and 3.00 mL of 0.25% 1,10-phenanthroline were added, and the solutions were diluted to the mark with distilled water. They were kept for 10 minutes before their absorbance was taken at a wavelength of 508 nm against a blank containing all the reagents except the iron solution. The concentration of iron was determined by extrapolating the sample absorbance value on the standard calibration curve; thereafter, the iron content in the samples was determined by taking into account the dilution factor.[19]

RESULTS

Sample Distribution: A total of 15 samples were analysed, consisting of 4 tablets, 5 capsules, and 6 syrups, all of which were within their respective shelf lives. In the dosage forms distribution, syrups make up 40%, capsules comprise 33.33%, and tablets account for 26.67% (Figure 2). The samples included both locally produced and imported products. Among the 15 brands evaluated, 12 (S1, S2, S3, S4, S6, S7, S10, S11, S12, S13, S14, and S15) were formulated in Nigeria, accounting for 80.00% of the total samples, whereas 3 brands (S5, S8 and S9), which constituted 20.00%, were imported from India (Figure 3). Each product was registered with the National Agency for Food and Drug Administration and Control (NAFDAC), which is the main governmental

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authority responsible for overseeing the production, distribution, and sale of drug and food products in Nigeria.

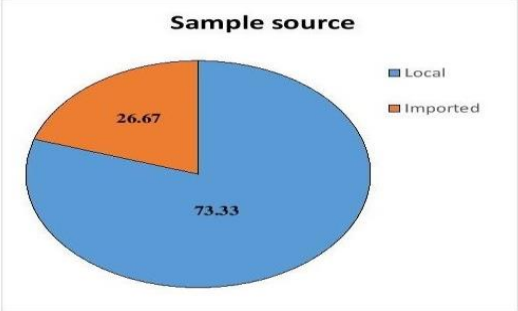

Figure 3: Distribution of the drug samples by source

Determination of iron content

UV-visible spectrophotometric analysis: Iron (Fe) was evaluated in various dosages and salt forms - ferrous sulphate, ferrous fumarate, ferrous gluconate, and ferric ammonium citrate - using the UV-visible spectrophotometric method. A standard Fe calibration curve (Figure 4), which was constructed as absorbance against concentration, facilitated the determination of iron content in the drug samples, listed in Table 2. According to the British Pharmacopoeia (BP) specifications, the acceptable limits for the labelled amounts of ferrous sulphate, ferrous fumarate, and ferrous gluconate in solid dosage forms are 98.0% to 105.0%, 93.0% to 101.0% (dried substance), and 11.8 to 12.5% of iron (II) (dried substance), respectively. In addition, the United States Pharmacopoeia (USP) sets the limit at 90% to 110% for ferrous ammonium citrate oral solution. The information provided by the manufacturer for the 15 samples is summarised in Table 1. Nine brands comprising two tablets (S3, S4), five capsules (S5, S6, S7, S8, S9), and two syrups (S10 and S15) adhered to the elemental iron specifications set by the BP and USP, as shown in Table 2. Conversely, six brands, which include two tablets (S1, S2) and four syrups (S11, S12, S13, and S14), had iron content that fell outside the established BP and USP specifications. All five capsule brands (S5 to S9) containing ferrous fumarate passed the assay test requirements for iron. In contrast, among the 4 tablets analysed, S1 and S2 did not meet the assay test, displaying iron content below the minimum limit defined by the BP, while S3 and S4 were successful in the assay test, showing percentage contents of 97.08% and 101.74%, respectively. The six syrups tested contain either ferrous gluconate or ferric ammonium citrate in different concentrations. Among the 12 samples analysed, 4 samples (S10, S12, S13, and S15) passed, with iron content within the limits specified by the BP and USP, whereas the iron content in S11 and S14 was significantly below the lower limit specified by the USP. Only 60% passed the assay test, while 40% failed, as depicted in Figure 5.

In the UV-visible spectrophotometric assay, the sample solution was treated with a complexing agent to form a coloured solution that absorbs light waves in the visible spectrum. Initially, iron was reduced to Fe^{2+} using hydroquinone (Figure 6), and subsequently complexed with 1,10-phenanthroline (Figure 7) to create a red-orange complex solution (Figure 8) that exhibits strong absorption in the visible spectrum at a wavelength of 508 nm. The wet digestion technique involving concentrated strong HCl was employed to decompose the drug matrix and release the iron into solution.

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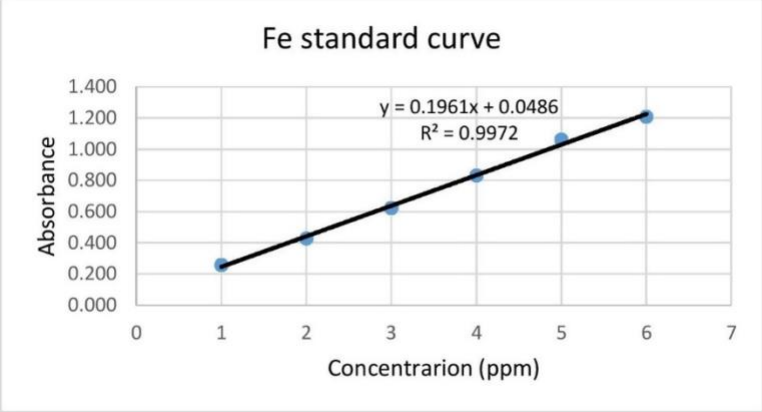

Figure 4: Standard calibration curve for iron (Fe) determination by UV-visible spectrophotometric method

Table 2: Amount of iron in the drug samples by UV-visible spectrophotometric method

Brand Code	Dosage form	Iron salt	Claimed content (mg)[a]		Determined content (mg)[b]		% Recovery
			Iron salt	Fe	Iron salt	Fe	Iron salt/Fe (%)
S1	Tablet	Ferrous sulphate	200	65	281.2	56.24	86.52
S2	Tablet	Ferrous sulphate	200	65	268.45	53.69	82.60
S3	Tablet	Ferrous sulphate	200	65	315.50	63.10	97.08
S4	Tablet	Ferrous sulphate	200	65	330.65	66.13	101.74
S5	Capsule	Ferrous fumarate	91	30	85.52	28.22	94.07
S6	Capsule	Ferrous fumarate	50	16	48.12	15.88	99.25
S7	Capsule	Ferrous fumarate	150	50	139.52	47.30	94.60
S8	Capsule	Ferrous fumarate	305	100	318.36	101.66	101.66
S9	Capsule	Ferric fumarate	55	18	49.79	17.11	95.06
S10	Syrup	Ferric ammonium citrate	32.18	7	30.98	6.53	93.29
S11	Syrup	Ferric ammonium citrate	80	16	68.28	14.39	89.94
S12	Syrup	Ferrous gluconate	120	14	128.42	15.41	102.73 (12.84)*
S13	Syrup	Ferrous gluconate	140	16	122.17	14.66	91.63 (10.47)*
S14	Syrup	Ferric ammonium citrate	54	11	87.31	18.40	167.27
S15	Syrup	Ferric ammonium citrate	200	41	197.24	41.57	101.39

a, b = average value of three determinations for each sample; * % recovery iron salt {percent of iron(II) (dried substance)}

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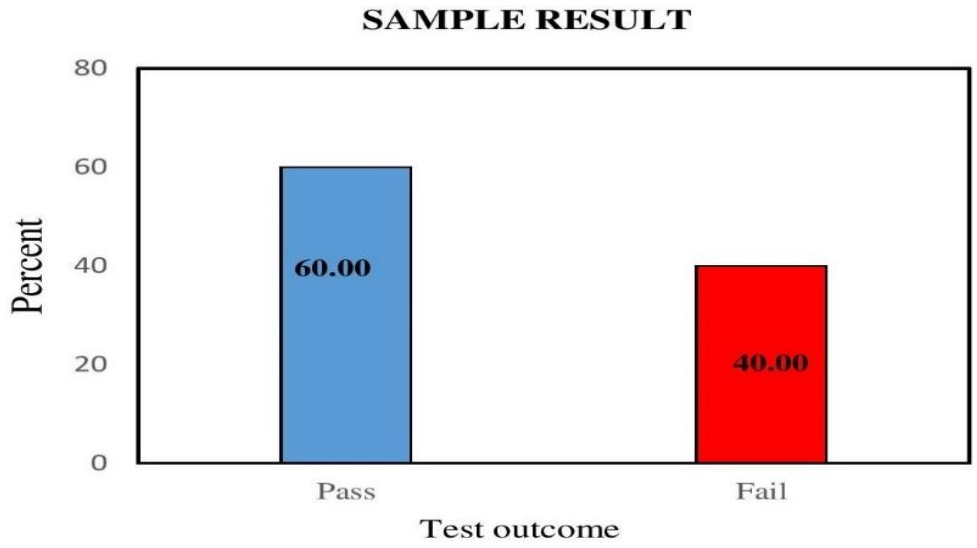

Figure 5: Assay test results

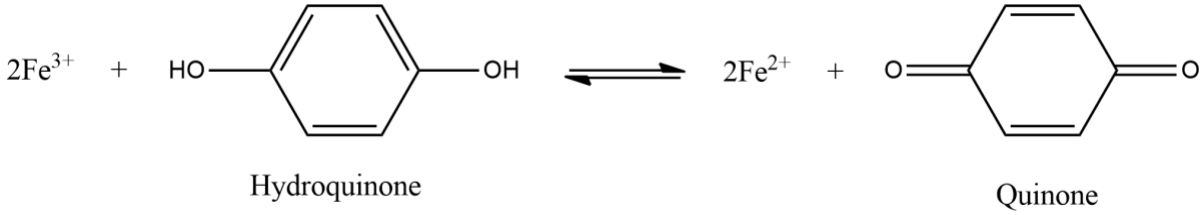

Figure 6: Reaction of iron with hydroquinone

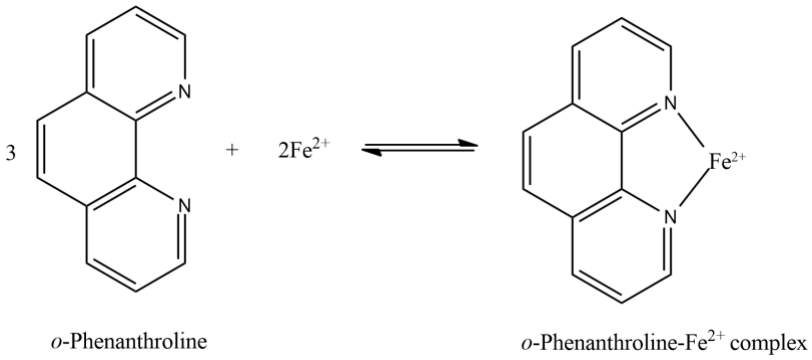

Figure 7: Reaction of Fe^{2+} with 1,10-phenanthroline

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Figure 8: Standard (a-f) and sample solutions (g-h) after complexing with 1,10-phenanthroline

DISCUSSION

Chemical analysis is essential for assessing pharmaceutical quality, especially regarding the concentration of active ingredients. Adherence to the purity criteria outlined in official pharmacopoeias provides a dependable measure of product quality. In the present study, various iron-containing salts—ferrous sulphate, ferrous fumarate, ferrous gluconate, and ferric ammonium citrate—were analysed using UV–visible spectrophotometry. Reported elemental iron contents in these salts are approximately 33% for ferrous fumarate, 20% for ferrous sulphate, and 12% for ferrous gluconate.[20,21] Although alternative techniques are available, which include redox titration with cerium(IV) ammonium sulphate, atomic absorption spectroscopy, and flame atomic absorption spectrophotometry (FAAS), each offering different levels of accuracy and precision, UV–visible spectrophotometry remains the most practical and widely adopted method for assaying iron in pharmaceutical formulations, particularly in resource-limited laboratory settings.[22] Though the choice of analytical techniques for the evaluation of iron in different pharmaceutical products depends greatly on the physical state or salt type.

It was found that syrups were the most prevalent dosage form among iron-containing products across the surveyed pharmacies in Ado Ekiti. This observation aligns with previous reports indicating that flavoured and medicated syrups are preferred owing to their palatability and ease of administration.[23] Despite this predominance, the study achieved an adequate distribution of dosage forms that reflects the local market composition. Most samples used in this study were locally manufactured, consistent with the broader Nigerian over-the-counter (OTC) market, where domestic firms supply the majority of OTC products. In contrast, prescription-only medicines (POM) and certain OTC formulations are more commonly imported from Asia, Europe, and North America. All fifteen products included in this study were approved by NAFDAC, suggesting that manufacturers complied with regulatory

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requirements and reduced the likelihood of deliberate falsification.

The iron content in the analysed drug samples varied in their conformity with the acceptable limits set out in the BP and USP across the three dosage forms, with syrups showing the lowest compliance. The majority of the tablets and all the capsule samples complied with BP and USP specified limits, confirming that these dosage forms show better stability of the active ingredients during manufacturing and storage.[24,25] Ferrous ions are more soluble in water than ferric ions but readily oxidize to ferric species and can form colloidal aggregates, which compromise the stability of liquid iron supplements and reduce bioavailability, thereby diminishing therapeutic efficacy.[26] A study in Ilorin, Nigeria, found that a substantial proportion of iron-containing products failed official chemical quality assays, indicating systemic quality-control deficiencies in some local pharmacies.[27] Similar deviation from pharmacopoeia specifications was observed in a study on iron-containing drugs sold in the Palestinian market, where 72% of sampled iron supplements exceeded standard limits.[28] A study conducted in Ghana documented discrepancies between labelled strength (50 mg/mL) and measured concentrations (above 50 mg/mL).[29] These inconsistencies pose significant public-health concerns for populations relying on such supplements to prevent or treat iron-deficiency anaemia.

Degradation of active ingredients during manufacturing and storage remains a significant challenge in the pharmaceutical industry. To offset potential losses, manufacturers sometimes formulate products with elevated levels of the active ingredients. Poor-quality iron preparations can harm patients. Low iron level in the body may cause fatigue, reduced energy, pallor, dyspnoea, and dizziness, and in severe cases can result in cardiac complications, impaired child development, and obstetric risks. Conversely, iron excess can cause organ damage, increase susceptibility to infection, and compromise immune function.[30] The present findings raise concerns about the quality of certain products circulating nationally and provide an evidential basis for regulatory action by the National Agency for Food and Drug Administration and Control (NAFDAC) to combat the distribution of counterfeit and unregistered medicines. The increasing availability of counterfeit products in local pharmacies underscores the need for sustained post-market surveillance to verify authenticity, composition, and compliance with pharmacopoeia standards. Routine quality assessments of non-prescription iron preparations, which are predominantly dispensed OTC, are frequently neglected. Although the study included a limited number of brands restricted to products available in Ado-Ekiti at the time of sampling, the data could inform NAFDAC's inspection scheduling, support prioritization of local laboratory testing, and justify implementation of a quality-seal program for compliant products—measures that would enhance transparency, protect consumers, and strengthen market competitiveness for manufacturers that meet regulatory standards.

CONCLUSION

UV–visible spectrophotometry provides a rapid, precise, and simple method for quantifying ferrous ion (Fe^{2+}) concentrations in iron-containing pharmaceuticals. Several samples deviated from pharmacopoeia specifications, warranting immediate regulatory quality-control assessments of haematinic products at pharmacy retail outlets in Ado-Ekiti. Public-education programmes on the appropriate use of iron preparations should target the vulnerable groups, including pregnant women, older adults, and clinically ill patients. Regulatory authorities must ensure strict enforcement of established standards and guidelines to protect product quality and public health.

Declarations

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Authors' Contribution: OUB and AAS contributed to the conception and study design, OUB, AAS, WMO, APB, OB, and JEG, contributed to the data acquisition and analysis, FMN supervised and validated the data analysis, and OUB drafted the manuscript. All authors critically revised and approved the final version of the manuscript for publication.

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