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Study the Effect of Storage Conditions on the Physicochemical Properties of Pharmaceutical Iron Supplements

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دراسة تأثير ظروف التخزين على الخصائص الفيزيائية والكيميائية لمكملات الحديد الصيدلانية

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الملخص:
يُستخدم الحديد بشكل شائع لعلاج فقر الدم، ويُصرف بوصفة طبية أو يُباع كدواء بدون وصفة طبية كمكمل غذائي في الصيدليات الحكومية. تم تحليل مكملات الحديد في الصيدليات الليبية لتحديد محتواها من الحديد. جُمعت ست عينات من أشكال دوائية مختلفة من مدينة الخمس. في هذه الدراسة، تم تحديد محتوى الحديد الفعلي باستخدام تقنية قياس الطيف الضوئي لتحديد الحديد في عينات مكملات الحديد، وهي: كبريتات الحديدوز (أقراص في عبوة)، وهيهايم (كبسولة)، وكبريتات الحديدوز (أقراص في مغلف)، وفيلفيت (أقراص في مغلف)، والحديد، **OPTiFer** (سائل). تعتمد الطريقة المقترحة على تفاعل الحديد Fe^{+2} مع 1-10 فينانثرولين ككاشف ملون. تم دراسة تأثير التخزين في درجة حرارة الغرفة على تركيز الحديد، وقيم الأس الهيدروجيني، والتوصيل الكهربائي لعينات مكملات الحديد. تم قياس امتصاص المحاليل القياسية والعينات عند 510 نانومتر. تم رسم منحنى المعايرة في نطاق تركيز من 1 إلى 6 جزء في المليون. تم الحصول على علاقة خطية بالمعادلة $y = 0.1772 + 0.0025$ ، ومعامل ارتباط $R^2 = 0.993$. الطريقة المقترحة بسيطة وحساسة وسريعة، ويمكن استخدامها لتحديد نسبة الحديد في الأدوية المُكمِّلة للحديد .

الكلمات الدالة: الأدوية المُكمِّلة، محتوى الحديد، قياس الطيف الضوئي، الخصائص الفيزيائية والكيميائية.

Abstract
Iron is commonly used to treat anemia and is prescribed or sold as an over-the-counter drug and as a food supplement in public pharmacies. The iron supplements in the Libyan pharmacies were analyzed for their iron content. Six samples of different pharmaceutical dosage forms were collected from Alkhums city. In the current study, the actual iron content was determined using the spectrophotometric technique for the determination of iron in supplement samples, namely Ferrous Sulphate (Tablets in a package), Hihaem (capsule), Ferrous Sulphate (Tablets in an envelope), VELVET (Tablets in an envelope), Ferrum, and OPTiFer (liquid) samples. The proposed method is based on the reaction of iron Fe^{+2} with 1-

10 phenanthroline as chromogenic reagent. The effect of storage at room temperature on the concentration of iron, PH values, and electrical conductivity (EC) of the iron supplement samples has been investigated. The absorbance of the standard solutions and the samples was measured at 510nm. The calibration curve was plotted in the concentration range of 1-6ppm. A linear relationship was obtained with the equation y=0.1772+0.0025 , and a correlation coefficient R^2=0.993. The suggested method is simple, sensitive, fast, and can be used for the determination of iron in iron supplement drugs.

Keywords: supplement drugs, iron content, spectrophotometric, physico-chemical properties.

Introduction

Iron is recognized as an essential mineral for the human body, playing various crucial roles. The body needs a certain level of iron to perform its vital functions. Iron, essential for our health, must be obtained through food as our bodies cannot naturally produce it; thus, we should incorporate iron-rich foods into our diet (Abbaspour et al., 2014). A regular diet that includes iron could supply sufficient amounts to compensate for the iron lost. It is among the most prevalent mineral deficiencies globally, leading to anemia. As a result, nutritional supplements, commonly referred to as iron supplements, to make up for the deficiency or the quantity of iron that has been lost (Nianyi et al., 2020).

Dietary or medicinal iron supplements contain iron at higher levels than those found in food and are available in various pharmaceutical forms, including tablets, capsules, syrup, injections, and drinking ampules(Ragiab et al., 2020 & Abualhasan et al., 2021). Iron is considered one of the essential minerals among vitamins, as it is vital for the human body. The typical amount of iron found in the human body is 3 to 4 grams. The majority of iron is in complex forms bonded to proteins, including haemoglobin and myoglobin. Iron is utilized for both preventing and treating iron-deficiency anaemia (Achrekar Swati 2022). Dietary supplements containing iron are commonly available. It functions to enhance red blood cell production (Barbosa et al., 2017).

According to the world health organization WHO, approximately 42% of pregnant women suffer from anemia globally. According to the (WHO, 2012), iron deficiency accounts for at least half of this anemia. A woman who is pregnant is deemed anemic if her hemoglobin level, measured during the initial and final trimesters of her pregnancy, is below 11.0 g/dL. Iron deficiency anemia IDA is termed when anemia is associated with iron deficiency (WHO, 2011). In particular, the Libyan Ministry of Health should take corrective actions, such as monitoring the registration and performing regular quality checks on local and imported pharmaceutical products

Several techniques have been used for iron determination. These techniques such as Spectrophotometry (Eldin and Alamary et al., 2017), potentiometric titration and atomic absorption (Abualhasan et al., 2021) , Double-Beam Direct Injection Flow Detector (Stanislawa 2021), voltammetric methods (Liu Hong et al., 2020 & Mohammad Amayreh and Mohammed Khair Hourani 2018) and chromatographic techniques (Virginia and German 2025 & Barbosa et al., 2017).

The aims in this study were to evaluate the effect of storage conditions on various pharmaceutical forms (packages, capsules, and liquid). A simple and accurate spectrophotometric technique was used for iron determination in iron supplements medicines, namely Ferrous Sulphate, Hihaem, Ferrous Sulphate, VELVET, Ferrum, and OPTiFer. The spectroscopic analysis method relies on the reaction of ferric oxide iron(II) with 1,10-phenantrolene, as shown in the following equation:

This complex is stable and exhibits a reddish colour that can be absorbed at a maximum wavelength (510 nm).

2. Material and Methods

2.1 Instruments

The absorption value (A) of all standard solutions and the absorption value of all sample solutions were measured using a digital spectroscopic absorption spectrometer with 1 cm quartz cell. A pH values of the studied sample solutions were measured using a pH metre. While the electrical conductivity (EC) was measured by a conductivity meter.

2.2 Chemical and Reagents

All chemicals were of analytical grade. Sodium acetate was obtained from BDH, England; Hydroxylamine HCl was obtained from RDH, Germany; 1,10-phenanthroline was obtained from Chemical Bull Pvt. Ltd, the iron used to prepare the standard solution was obtained from Winlab, UK. Freshly distilled and deionized water was used throughout the experiment.

2.3 Preparation of Standard Solution

A series of standard solutions were prepared to construct the calibration curve. These solutions were prepared at concentrations of 1, 2, 3, 4, 5 and 6 ppm. 15, 12.5, 10, 7.5, 5, and 2.5 ml of iron(II) solution were transferred to a series of 25 ml standard flasks. 2 ml of 1% hydroxylamine hydrochloride solution, 2 ml of sodium acetate solution (1M), and 2 ml of 1% phenantroline solution were added to each flask and diluted to the volumetric mark using distilled water. The blank solution was prepared by transferring 2 ml of 1% hydroxylamine hydrochloride solution, 2 ml of sodium acetate solution (1M), and 2 ml of 1,10-phenantroline solution to a 25 ml standard flask and filling the flask to the volumetric mark with distilled water.

The iron supplement samples in their various pharmaceutical forms (packages, capsules, and liquid) were collected from different pharmacies in Al-Khums city. As shown in Table 1.2, the samples used for analysis include the brand name, place of origin, medicinal composition, pill shape, and dosage amount.

Table 1.2 Description of the iron supplement samples used in the analysis

Sample number	Brand name	Origin	Medicine composition	Shape of medicine	Dose amount
1	Ferrous Sulphate	UK	Food supplement containing ferrous sulfate	Tablets in a package	200mg
2	Hihaem	Egypt	Dietary supplement containing iron, zinc and glycine ferrous sulfate	Capsule	100mg

3	Ferrous Sulphate	UK	Food supplement containing ferrous sulfate	Tablets in an envelope	200mg
4	VELVET	UK	A dietary supplement containing iron, folic acid, zinc,and ferrous bioglycinat	Tablets in an envelope	150mg
5	Ferrum	Turkey	A food supplement containing iron, folic acid, and polymaltose.	Liquid	50mg/5ml
6	OPTiFer	Tunis	A dietary supplement containing iron, folic acid, vitamin C, vitamin B12, zinc, and ferrous pyrophosphate.	Liquid	14mg/5ml

3. RESULTS and DISCUSSION

3.1 Calibration Curve

Figure 3.1 shows the calibration curve for iron (II) in the buffer solution. The absorbance of the standard solutions and the samples were read at 510nm. The calibration curve was plotted in the concentration range of 1-6ppm at 510nm. A linear relationship was obtained with the equation y=0.1772+0.0025 , and a correlation coefficient R^2=0.993, which has been used for the determination of the iron (II) concentration in the investigated samples.

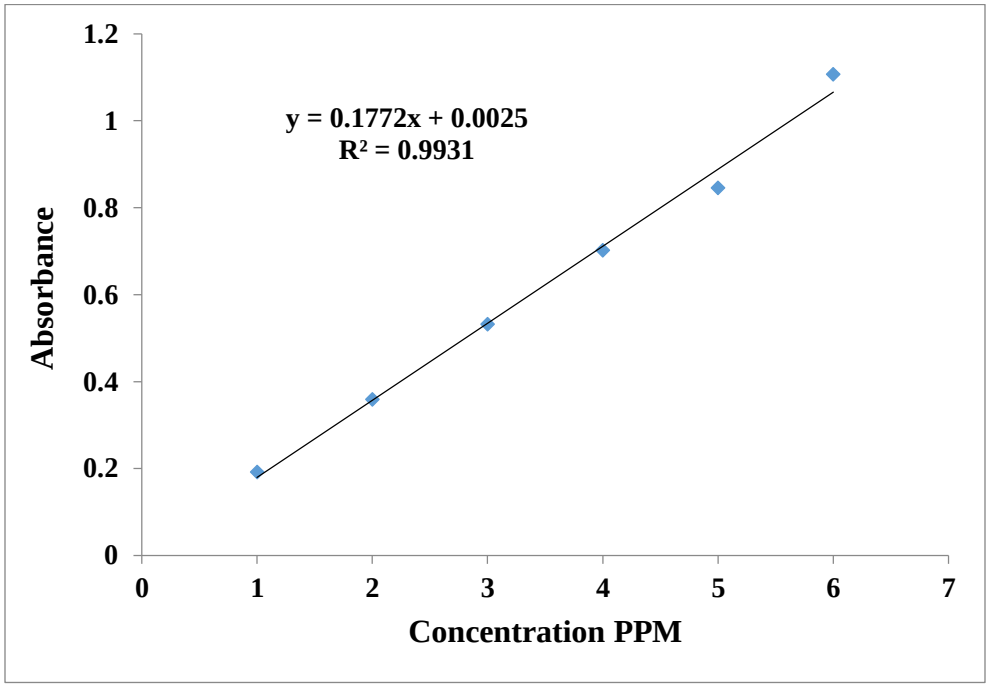

Figure 3.1 The calibration curve of Iron (II) determination

3.2 The effect of storage at room temperature on the concentration of the studied samples

In this study the temperature and humidity during the storage period were in the range of (14C° to 24 C°) and (47% to 73%), respectively. Samples (1, 2 and 3) contain ferrous sulfate as the active ingredient. The effect of storage at room temperature on the concentration of the studied samples can be clearly seen in figure 3.2. The results obtained show a decrease in the concentration of the active ingredients in the samples (1, 2 and 3) during the storage period (four weeks). This decrease is attributed to the transformation of iron from the oxidized state of Fe^{+2} to Fe^{+3}. Furthermore, this result could be attributed to the effect of temperature and humidity on the efficacy of the samples, leading to a loss of their therapeutic properties, a similar result was obtained by Elhagi et al., 2012 and Gozdyra et al., 2011.

On the other hand, as shown in figure 3.2 the concentration of the iron studied samples (4, 5 and 6) were increased during the storage period. The sample (4), containing ferrous ascorbate, folic acid, and zinc sulfate as its active ingredients while the samples (5 and 6) are liquid iron supplements. There is a dramatic increase in the concentrations due to the sugar content in these samples, which led to hydrolysis during the storage period, altering their concentrations and increasing sample absorption, This behaviour is similar to previous reported by Poulami et al.,2025

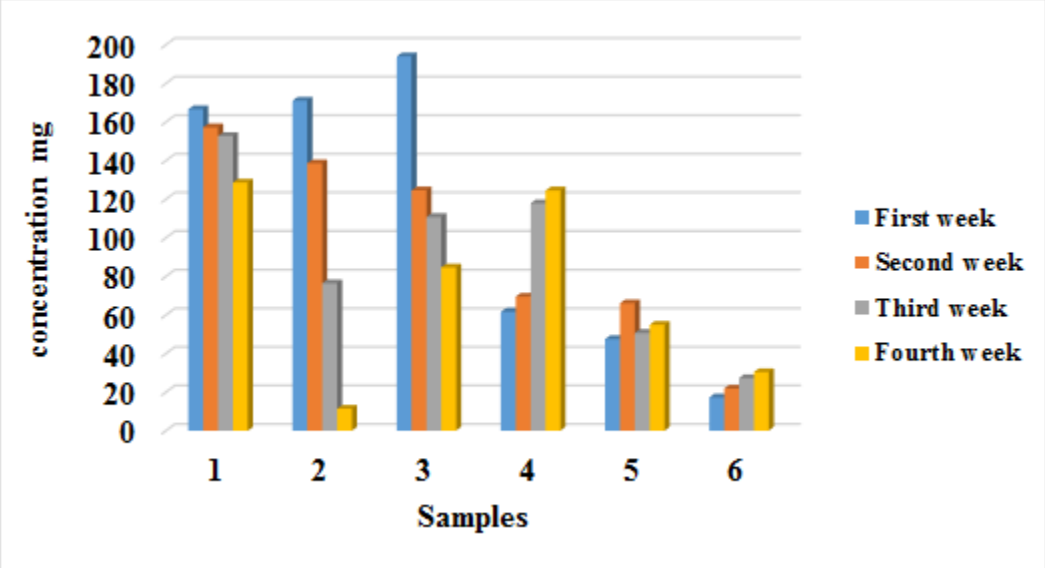

Figure 3.2 The effect of storage on the concentration of the studied samples

3.3 The effect of storage at room temperature on pH

The pH value of the studied samples was investigated and the obtained results are shown in figure 3.3. This property is affected by storage and temperature. The results showed that the pH of the sample (1) increased over four weeks of storage period, due to the reduction of the ferric ions to ferrous ions Fe^{+3} to Fe^{+2} (Abbaspour et al., 2014). The pH of the sample (2) decreased gradually over the storage period, indicating an increase in the acidity of the solution. Furthermore, this result could be attributed to the decomposition of glycinated iron sulfate. The pH of the sample (3) increased, particularly in the second week. In the sample (4) The PH values were decreased during the storage period (four weeks), due to the chemical composition of the tablets, which makes unstable complexes during storage at room temperature (Szewczyk et al., 2021).

However, the pH values of the samples (5 and 6) decreased over the storage period due to the chemical composition. In addition, sample (5), which consists of iron-containing polysaccharides, is susceptible to bacterial contamination, which contributes to increased acidity (Blight et al., 2012 & Abualhasan et al., 2021).

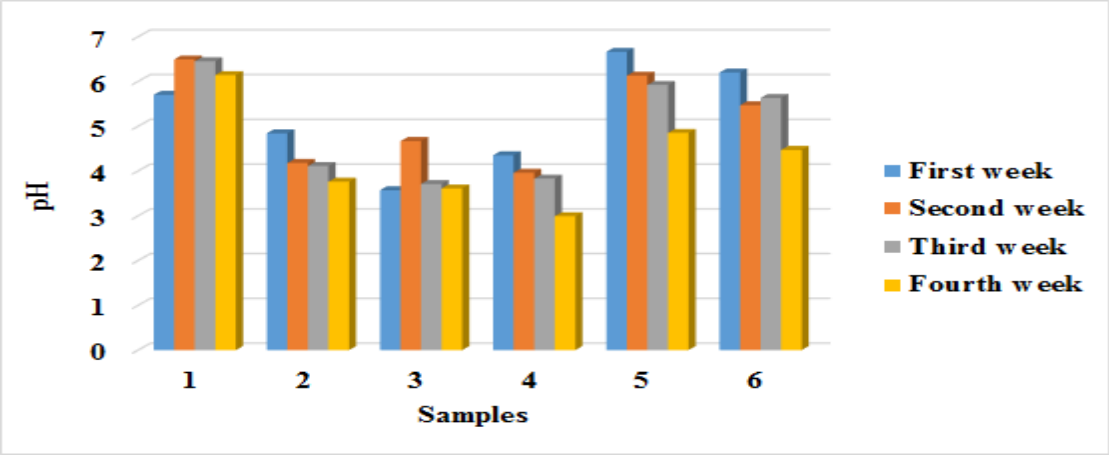

Figure 3.3. The effect of storage at room temperature on pH

3.4 The effect of storage at room temperature on electrical conductivity (EC)

Electrical conductivity is a method for measuring the concentration of an electrolyte solution. The drug's properties, such as chemical composition, sugar content, salt content, and pH, affect the electrical conductivity. In addition, the ambient temperature affects the electrical conductivity of the drug supplements. Since the studied samples are ionic solutions, the conductivity decreases with decreasing ion concentration in the solution (Bakre et al., 2016 & Yoshino et al., 2011).

The effect of storage at room temperature on electrical conductivity (EC) can be seen in figure 3.4. The results obtained show the highest conductivity value of (1156 µS) for the sample (1) in the first week, and the lowest value of (125 µS) for the sample (6) in the third week. In general, the electrical conductivity values of the studied samples decreased gradually during the storage period. The decrease in conductivity is attributed to the effect of the temperature on the active ingredients in the drug supplements (Regberg 2011).

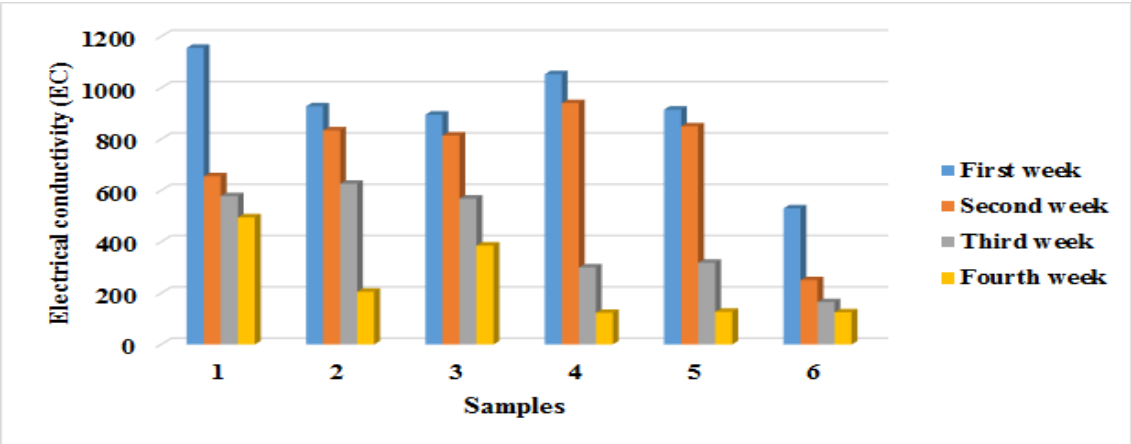

Figure 3.4. The effect of storage at room temperature on electrical conductivity (EC)

4. Conclusion

The current study revealed that the studied samples were affected by storage conditions, which altered their physical and chemical properties and reduced their effectiveness. Since most iron supplements consist of various salts, unsuitable storage conditions accelerated these changes, further diminishing the drug's efficacy.

Exposure of pharmaceutical iron supplements to elevated temperatures and humidity can lead to changes in appearance, reductions in iron content, altered dissolution and disintegration characteristics, and decreased product quality. These changes may compromise the efficacy and shelf life of the iron supplements.

These findings emphasize the importance of proper storage practices during manufacturing, transportation, distribution, and patient use. Adhering to recommended storage conditions is essential to ensure that pharmaceutical iron supplements remain safe, effective, and of high quality until their expiration date.

Therefore, the agency must assume responsibility for quality control of pharmaceutical products before it is given to patients. Since there are significant side effects associated with the iron content, including anemia, lethargy, and heart palpitations, overdosing may be associated with appreciable morbidity and mortality cases.

We are completely aware that this article has some limitations. These include: further long-term stability studies involving different iron formulations and packaging materials. Therefore, future studies should investigate these factors in pharmaceutical supplements to understand their effect on product stability and to improve storage recommendations.

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