PERCENTAGE OF IRON CONTENT IN PHARMACEUTICAL PREPARATION : A REVIEW OF ANALYTICAL METHOD

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ABSTRACT

Iron is an essential element required for haemoglobin formation and several physiological processes. Iron-containing pharmaceutical products are available in different dosage forms, and the quantity of iron present should be consistent with the declared label claim. This project reviews published analytical approaches for determining iron in pharmaceutical preparations, with emphasis on UV–Visible spectrophotometry using 1,10-phenanthroline. Alternative methods discussed include atomic absorption spectrometry (AAS), sequential injection analysis, flow-based photometry, conductivity monitoring, computer-vision analysis, and infrared spectroscopy combined with chemometrics.

The uploaded review compiles data from 12 source articles and reports that iron content in most investigated oral solid dosage forms was approximately 96–106% of the labelled amount. Reported exceptions included a gelatin-capsule sample at 80.7%, some products near 90%, and one product at 107.6%. These are published literature findings and are not results from the present student project. A proposed laboratory study is outlined to estimate iron in selected marketed tablets, construct a calibration curve, calculate percentage label claim, and evaluate relevant analytical performance characteristics. Actual experimental results must be generated and documented before conclusions are drawn about the selected products.

Keywords: iron, pharmaceutical analysis, UV–Visible spectrophotometry, 1,10-phenanthroline, label claim, assay, quality control, assay of iron, method of validation, iron determination, analytical method, percentage label claim, atomic absorption spectroscopy etc.

1. INTRODUCTION

Iron is an essential trace element involved in haemoglobin formation, oxygen transport, cellular respiration, and enzyme function. Iron deficiency may lead to iron-deficiency anaemia, and oral iron preparations are commonly used when supplementation is clinically indicated. Common oral preparations include ferrous sulfate, ferrous fumarate, and ferrous gluconate; iron is also available in other complexes and dosage forms [1,2].

Pharmaceutical quality control includes verifying the identity, strength, purity, and consistency of a product. For iron-containing preparations, an assay helps determine whether the amount of iron measured in a sample corresponds to the amount declared on the label. Differences may result from manufacturing variability, formulation matrix effects, sampling, sample preparation, or limitations of the analytical procedure [1–4].

UV–Visible spectrophotometry is useful in teaching and quality-control laboratories because it is relatively accessible and can provide quantitative measurements when the method is appropriately developed and validated. In the 1,10-phenanthroline method, ferrous ions form an orange-red complex whose absorbance can be related to concentration using a calibration curve [2,3]. Alternative methods may be appropriate where automation, low reagent consumption, or different analytical capabilities are required [4–7].

The uploaded source review summarise studies on oral tablets, capsules, sachets, liquids, dissolution behaviour, and intravenous iron complexes. Since the dosage forms and reported units differ, results from separate studies should not be treated as directly interchangeable.

2. AIM AND OBJECTIVES

2.1 Aim

To review analytical methods for estimating iron in pharmaceutical preparations and outline a UV–Visible spectrophotometric procedure for the determination of iron content in selected marketed tablets.

2.2 Objectives

- To review published analytical methods used for iron determination in pharmaceutical products.
- To describe the principle of the 1,10-phenanthroline spectrophotometric method.
- To outline preparation of standards and pharmaceutical sample solutions.
- To calculate iron content and percentage of label claim from measured data.
- To identify relevant method-performance characteristics, including linearity, accuracy, precision, and specificity.
- To compare spectrophotometry with selected alternative analytical techniques.

3. REVIEW OF LITERATURE

3.1 UV–Visible spectrophotometry using 1,10-phenanthroline

Rajbhandari and colleagues compared spectrophotometry with atomic absorption spectroscopy for iron tablets. Their spectrophotometric method relied on formation of a ferrous tris(1,10-phenanthroline) complex after suitable sample treatment. The authors reported broadly comparable measurements by the two techniques for the tablets investigated [2].

Parajuli and colleagues used 1,10-phenanthroline to quantify iron in different pharmaceutical products. Their study illustrates the use of a calibration-based spectrophotometric approach for measuring iron in tablet samples [3]. The uploaded review reports that the investigated products were generally close to their labelled values, but one gelatin-capsule sample was reported at 80.7% of label claim [3].

3.2 Sequential injection analysis

Tesfaldet and colleagues reported sequential injection spectrophotometric determination of iron in multivitamin preparations using 1,10-phenanthroline. Automation of reagent and sample handling can improve throughput and reduce manual handling, although the method still requires suitable calibration and control of potential interferences [4].

3.3 Flow-based photometric methods

Koronkiewicz developed a double-beam direct-injection flow detector for iron determination in pharmaceutical products. The published report describes a linear range of 1–30 mg/L, a detection limit of 0.5 mg/L, a throughput of up to 90 samples per hour, and repeatability expressed as 2% relative standard deviation under the reported conditions [5].

3.4 Green colorimetric analysis

Siriangkhawut, Ponhong, and Grudpan investigated aqueous guava-leaf extract as a natural reagent for colorimetric iron determination. The method was applied to pharmaceutical samples and compared with flame atomic absorption spectrometry. The authors reported recovery values of 93–99% and agreement with the reference method under the study conditions [6].

3.5 Computer-vision analysis

Solana-Altabella and colleagues developed camera- and scanner-based analytical methods using image analysis to quantify iron in commercial pharmaceutical formulations. Their reported results were comparable with spectrophotometric and pharmacopoeial methods, suggesting that image-based analysis may be a lower-cost option when carefully controlled and validated [7].

3.6 Conductivity as an alternative measurement

Lisik and colleagues evaluated electrical conductivity as an alternative means of monitoring the release of ferrous ions during dissolution testing. The method was partially validated and compared with atomic absorption spectrometry. The authors noted acceptable performance for three of four formulations studied, while one formulation showed high variability [1]. This method assesses release behaviour and should not automatically be treated as equivalent to a direct total-iron assay.

3.7 Iron preparations and pharmacological context

Geisser and Burckhardt reviewed pharmacokinetic and pharmacodynamic considerations for iron preparations, including differences between oral iron salts and intravenous iron complexes. This background is relevant because formulation type and iron chemistry affect the interpretation of analytical measurements [8].

4. PRINCIPLE OF THE ANALYTICAL METHOD

The proposed method is based on formation of an orange-red complex between ferrous ions (Fe^{2+}) and 1,10-phenanthroline. Iron in the sample is first brought into solution using a suitable sample-preparation procedure. If total iron is to be measured, ferric iron (Fe^{3+}) must be reduced to the ferrous state under the conditions specified by the selected method. The complex absorbance is measured at the wavelength established during method development; published methods in the uploaded review report wavelengths around 508–512 nm [2–4].

A calibration curve is prepared by measuring absorbance for standards of known iron concentration. Within the validated linear range, the absorbance of a sample is used to estimate its iron concentration. The calibration equation, dilution factors, and sample quantity are then used to calculate iron content per tablet.

5. MATERIALS AND INSTRUMENTS

5.1 Materials and reagents

- Selected marketed iron tablets with clearly stated elemental iron content.
- Suitable iron reference standard or certified standard solution.
- 1,10-phenanthroline reagent.
- Appropriate reducing agent, buffer or acid solution as required by the selected validated procedure.
- Distilled or deionised water.
- Reagent blank and suitable quality-control solutions.

5.2 Instruments and glassware

- UV–Visible spectrophotometer with suitable cuvettes.
- Analytical balance.
- Volumetric flasks and pipettes.
- Beakers, glass rods, and sample containers.
- Mortar and pestle.
- Suitable filtration equipment.

The exact reagent concentrations, sample preparation, and operating conditions must be selected from a suitable published method or an approved laboratory protocol and confirmed by the project supervisor. Laboratory work should be performed under appropriate supervision.

6. PROPOSED EXPERIMENTAL METHODOLOGY

Important: The following is a proposed protocol outline, not a record of completed experiments. It must be finalised and approved by the project guide before laboratory use.

6.1 Sample selection and documentation

Select the number of marketed iron tablet products specified by the project protocol. Record brand/product name, batch number, expiry date, dosage form, label claim expressed as elemental iron, and source of purchase. Use a documented sampling plan.

6.2 Preparation of standard solutions

Prepare a stock solution using an appropriate reference standard or use a certified iron standard. Prepare working standards by accurate dilution to cover a suitable concentration range. Record the standard identity, concentration, preparation date, and calculations.

6.3 Calibration curve

1. Prepare a reagent blank and a series of iron standards of known concentrations.
2. Add the required reagents according to the selected method.
3. Allow colour development for the specified time under controlled conditions.
4. Measure absorbance at the selected wavelength against the reagent blank.
5. Plot absorbance against iron concentration and calculate the calibration equation and coefficient of determination.

6.4 Tablet sample preparation

6. Record individual tablet weights and calculate the average tablet weight.
7. Powder a representative number of tablets using clean equipment.
8. Weigh a suitable portion corresponding to a known amount of the declared iron content.
9. Extract or dissolve the iron using the approved sample preparation procedure.
10. Filter if required and dilute quantitatively to a known volume.
11. Apply the required reduction and colour-development steps, then measure absorbance under the same conditions as the standards.

The extraction procedure should be appropriate for the formulation and should provide adequate recovery. Matrix effects should be investigated rather than assumed absent.

6.5 Analytical validation / performance assessment

- Linearity: assess the relationship between concentration and absorbance over the intended range.
- Accuracy: perform recovery experiments or compare with a suitable reference method where available.
- Precision: assess repeatability using independently prepared replicates; consider intermediate precision if required.
- Specificity: evaluate potential interference from excipients and other components.
- Range: establish the concentration interval over which performance is acceptable.
- Robustness: evaluate small deliberate changes in method conditions where required.
- Detection and quantitation limits: determine where appropriate to the intended use.

Validation requirements should be aligned with the current applicable ICH guidance, the chosen analytical purpose, and institutional requirements. Do not report validation as successful until the supporting measurements and calculations are available.

7. CALCULATIONS

7.1 Calibration equation

$A = mC + b$

Where A is measured absorbance, C is iron concentration, m is the calibration slope, and b is the intercept. Therefore, $C = (A - b) / m$.

7.2 Percentage of label claim

Percentage of label claim = (Measured iron content per tablet ÷ Labelled iron content per tablet) × 100

Measured and labelled iron quantities must be expressed in the same units. Apply all dilution factors and account for the exact sample mass before calculating iron content per tablet.

7.3 Mean and standard deviation

For replicate measurements, report the mean and standard deviation (SD). If appropriate, relative standard deviation (RSD, %) may be calculated as (SD ÷ mean) × 100.

8. DISCUSSION

The literature reviewed supports UV–Visible spectrophotometry with 1,10-phenanthroline as a practical method for estimating iron in suitable pharmaceutical preparations. It is comparatively accessible and provides a direct calibration-based measurement. The method nevertheless depends on complete sample preparation, suitable conversion of iron to the required oxidation state, controlled colour development, and evaluation of matrix interference [2–4].

In the uploaded review, most oral solid dosage forms were reported at approximately 96–106% of label claim. Exceptions included a gelatin capsule sample at 80.7%, some ferrous sulfate/fumarate samples near 90%, and one flow-method result at 107.6% [3,5,6]. These results should not be interpreted as evidence about all products currently on the market; they describe the samples and conditions in the cited studies.

AAS offers an established elemental measurement approach, while flow-based techniques may improve throughput and reduce reagent consumption. Computer vision and natural-reagent colorimetry are potential lower-cost approaches, but their suitability depends on appropriate calibration, control of lighting or reagent conditions, and validation [5–7]. Conductivity measurements may be useful for monitoring dissolution or release but do not necessarily measure total iron content in the same way as a direct assay [1].

The proposed laboratory work would allow a student to practise sample preparation, calibration, quantitative calculations, and basic method-performance assessment. Until the work is performed, no conclusion should be made about the measured iron content or quality of the selected samples.

9. LIMITATIONS

- The literature review combines independent studies using different methods, formulations, units, and sampling plans.
- Published values may not be directly comparable across studies.
- The proposed laboratory procedure requires supervisor approval and method-specific optimisation.
- Excipients or other ingredients may interfere with the analytical response.
- No original experimental results are included in this draft.
- Results from a limited selection of products cannot establish the quality of all iron-containing products.

10. CONCLUSION

The reviewed literature indicates that 1,10-phenanthroline UV–Visible spectrophotometry is a useful method for estimating iron in suitable pharmaceutical preparations. Alternative approaches—including atomic absorption spectrometry, flow-based photometry, natural-reagent colorimetry, computer-vision analysis, and conductivity monitoring—have also been investigated for particular analytical purposes. Published studies generally found iron content near label claim in the oral products tested, with some notable deviations. The proposed B.Pharm project provides a structured approach for estimating iron content, calculating percentage label claim, and assessing analytical performance. Final conclusions about selected marketed products must be based on actual laboratory measurements and documented validation.

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