Fe(II) in iron sucrose injection (USP)

Polarographic determination of limit of iron(II) according to USP–NF

Iron sucrose injection is a medical product commonly used for the treatment of iron deficiency anemia. Iron sucrose is a dark brown liquid which contains sucrose and iron(III) hydroxide in an aqueous solution. Once administered to the blood stream the iron (III) is stored in the protein ferritin where it is available for the production of the protein hemoglobin as a part of the red blood cells, which are essential for the transport of oxygen.

As a medical product, iron sucrose is subject to strict controls. Among other tests, the U.S. Pharmacopeia (USP) requires to monitor the limit of Fe(II) in the iron sucrose injection solution by polarography. The benefit of polarography is that Fe(II) and Fe(III) show signals at different potentials, and therefore an easier determination of Fe(II) without a previous separation of the two oxidation states is possible.

The 884 Professional VA together with the viva software allows a straightforward determination of the Fe(II) content of iron sucrose injection solution following the requirements of the USP. The Fe(II) content is automatically calculated and stored in a database together with all relevant determination and calculation parameters.

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SAMPLE

Iron sucrose injection solution ampoules

EXPERIMENTAL

The concentration of Fe(II) is determined in iron sucrose injection solutions using polarography. Sodium acetate supporting electrolyte is deaerated for 5 minutes. Then the sample is added, and the polarogram is recorded using the parameters listed in Table 1.

Figure 1. 884 Professional VA.

Table 1. Parameters

Parameter	Setting
Working electrode	SMDE
Mode	DP – Differential Pulse
Start potential	-0.1 V
End potential	-1.75 V
Peak potential Fe(III) -> Fe(II)	-0.75 V
Peak potential Fe(II) -> Fe^0	-1.4 V

ELECTRODES

- Working electrode: Multi-Mode Electrode pro with standard glass capillaries

- Reference electrode: Ag/AgCl/KCl (3 mol/L) reference electrode with electrolyte vessel. Bridge electrolyte: KCl (3 mol/L)
- Auxiliary electrode: Platinum rod electrode

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Two signals are recorded, one for the reduction of Fe(III) → Fe(II), and the second for the reduction of Fe(II) → Fe⁰. The concentration of Fe(II) is calculated as follows:

$$w(Fe^{2+}) = \left[1 - \frac{2}{R}\right] \times w(Fe(total)) \quad \left[\%w/v\right]$$

in which R is defined as:

$$R = \frac{peak\ height\ (Fe^{2+} \rightarrow Fe^0)}{peak\ height\ (Fe^{3+} \rightarrow Fe^{2+})}$$

The total iron concentration w(Fe(total)) is determined in a separate analysis by AAS (atomic absorption spectroscopy).

The calculation in this application can be done automatically in the **viva** software.
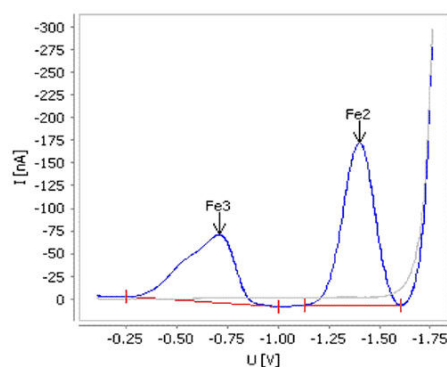

Figure 2. Determination of iron in iron sucrose injection

Table 2. Result

Sample	Fe(II) concentration
Iron sucrose injection	0.33%

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REFERENCE

United States Pharmacopeia USP 39–NF 34

Internal references: AW CH4-0452-112006; AW VA   CH4-0565-042017

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