Edition: BP 2025 (Ph. Eur. 11.6 update)

Ferric Chloride Injection

General Notices

Iron Chloride Injection

NOTE: This monograph has been developed to cover unlicensed formulations.

Action and use

Used in parenteral nutrition solutions.

DEFINITION

Ferric Chloride Injection is a sterile solution of Ferric Chloride Hexahydrate in a suitable liquid.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements. Where appropriate, the injection also complies with the requirements stated under Unlicensed Medicines.

Content of ferric iron, Fe(III)

90.0 to 110.0% of the stated amount.

IDENTIFICATION

Yields reaction C characteristic of *iron salts* and reaction A characteristic of *chlorides*, Appendix VI.

TESTS

Acidity

pH, 1.7 to 2.4, Appendix V L.

5-Hydroxymethylfurfural

Injections prepared in Glucose Infusion comply with the following test.

Dilute a volume containing the equivalent of 1.0 g of glucose, $C_6H_{12}O_6$, to 250 mL with *water*. The *absorbance* of the resulting solution at the maximum at 284 nm is not more than 0.25, Appendix II B.

ASSAY

Carry out the method for *inductively coupled plasma-atomic emission spectrometry*, Appendix II G1, using a wavelength of 238.2 nm.

Dilute a quantity of the injection with sufficient 2% v/v *heavy metal-free nitric acid* to produce a solution containing 0.001% w/v of Fe.

Calculate the content of Fe in the injection from a calibration curve obtained from a series of reference solutions prepared in the following manner. Dilute 1 volume of *iron standard solution (0.1% Fe)* to 10 volumes; dilute separate 0, 5, 10 and 20 mL quantities of the resulting solution to 100 mL with 2% v/v *heavy metal-free nitric acid*.

LABELLING

The strength is stated as the equivalent amount of iron, Fe, in a suitable dose volume.