



Certificate of Analysis

Productname: Ferri subsulfas solutio

Inspection No: I04079/0521/536
Batchnumber: 21B25-T03-086617
Expiration date: 31.01.2023
Analysed according to: USP
Original Manuf. Date: 1.2.2021

Sample Unit: 0 x
Batch Size: 100 x 500 ml

Identification of producer: V01589
Batch no. of vendor: 3097474

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Reddish brown liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Brownish-red precipitate	Fagron CZ
Identification B	Conform	Conform		Blue precipitate	Fagron CZ
Identification C	Conform	Conform		White precipitate	Fagron CZ
TESTS					
Nitrate	Conform	Conform			Fagron CZ
Ferrous salts	Conform	Conform			Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Iron	20 - 22	20	g/100ml		Fagron CZ

Qualified person correction

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
 PharmDr. Ivana Urbánková, QA

Date: 21.06.2021

Conclusion: APPROVED

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	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521



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Responsible: Ing. Mgr. Kateřina Jokešová, QC
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Date: 03.06.2021

Conclusion: APPROVED

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