

Certificate of Analysis

Productname: Ferri subsulfas solutio

Inspection No: I07612/1121/536
Batchnumber: 21B25-T03-090737
Expiration date: 31.01.2023
Analysed according to: USP
Original Manuf. Date: 1.2.2021

Sample Unit: 0 x
Batch Size: 360 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	$\leq 2 \times 10^3$	Conform	CFU/g		Contract Lab
TYMC	$\leq 2 \times 10^2$	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

The product conforms to USP.

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 05.10.2021

Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

This document has been produced electronically from our quality system and is valid without signature.

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521