

Certificate of Analysis

Productname: Ferri subsulfas solutio

Inspection No: I03083/0421/536
Batchnumber: 21B25-T03-085618
Expiration date: 31.01.2023
Analysed according to: USP
Original Manuf. Date: 1.2.2021

Sample Unit: 0 x
Batch Size: 500 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

Performed by: Lucie Kubáňová DiS.

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


Date: 05.05.2021

Conclusion: APPROVED

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