Fagron personalizing medicine

Certificate of Analysis

Productname: **Ferri subsulfas solutio**

Inspection No: I09523/1221/536
Batchnumber: **21J19-T24-091432**
Expiration date: 31.03.2023
Analysed according to: USP
Original Manuf. Date: 1.4.2021

Sample Unit: 0 x
Batch Size: 577 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
Itentification 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 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<10	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	21	g/100ml		Fagron CZ

The product conforms to USP.

Performed by: Lucie Kubáňová DiS.

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

Date: 08.12.2021

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) Kontrolní laboratoř č. 536	**Address** **Post Code**	Holická 1098/31m, Olomouc 779 00	**Phone No.** **Fax No.**	+420585222590 +420 585 226 521