

Certificate of Analysis

Productname: Ferri oxidum rubrum
Number of analysis/Inspection Code: 1 / KEUR-198692B
Batchnumber: 23L08-F01-385587
Reference code / No.: 4576 / W364L
Analysed according to: USP NF 23/3

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Brown) red powder	Conform		
Identification	Iron	Conform		
Water-soluble substances	<=1,0	0,3	%	
Acid-insoluble substances	<=0,3	0,0	%	
Organic colors and lakes	350 - 750	Conform	nm	
Mercury	<=3	<3	µg/g	
Arsenic	<=3	Conform	µg/g	
Lead	<=0,001	Conform	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Ferric oxide	97,0 - 100,5	99,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Nitrosamine impurities	Art. 5(3) of Reg. (EC) No 726/2004	Conform		Data producer

Analysis performed by the authorized laboratory Fagron Sp. z o.o. (PL).

Manufacturer / Country : Oxerra Italy SpA / IT
CEP : Not available

Release:
Anthony Amoureux
Qualified Person

29-02-24

Expiration: 24-10-24

Conclusion: APPROVED

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