

Certificate of Analysis

Productname: Ferri oxidum rubrum
Number of analysis/Inspection Code: 1 / KEUR-193649B
Batchnumber: 18K05-B01-379950
Reference code / No.: 4576 / W204A
Analysed according to: USP 41

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | (Brown) red powder | Conform | | |
| Identification | Iron | Conform | | |
| Water-soluble substances | <=1,0 | <1,0 | % | |
| Acid-insoluble substances | <=0,3 | <0,3 | % | |
| 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 | 98,5 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Eurofins.

Release:
Anthony Amoureux
Qualified Person

02/10/22

Expiration: 07-2023

Conclusion: APPROVED

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