

Batch No 3150683
Released by Thomas Poppe
Man./Release Date 11/11/2024
Retest Date 10/11/2026

Certificate of Analysis

Ferrous Fumarate

Powder, Ph.Eur.11.Ed.

Our. conf. No 000000000
Your order example
Quantity 0.0 kg
DPL-Code No 505025001
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Printing Date Emmerthal, 22/08/2025

Parameters	Limits	Results
Description	powder	powder
Colour	reddish brown	reddish brown
Identification TLC (Ph.Eur.)	conforms	conforms
Identification B (Ph.Eur.)	positive	positive
Identification Ferrous Iron	positive	positive
Sulfate (SO ₄)	max. 0.2 %	< 0.2 %
Ferric iron (FeIII)	max. 2.0 %	< 2.0 %
Arsenic (As)	max. 1.5 ppm	< 1.5 ppm
Lead (Pb)	max. 3 ppm	< 3 ppm
Chromium (Cr)	max. 200 ppm	< 200 ppm
Cobalt (Co)	max. 20 ppm	< 20 ppm
Nickel (Ni)	max. 50 ppm	< 50 ppm
Vanadium (V)	max. 40 ppm	< 40 ppm
Zinc (Zn)	max. 0.05 %	< 0.05 %
Loss on drying (105°C)	max. 1.0 %	0.6 %
Assay Ph.Eur. (on dried basis)	93.0-101.0 %	95.7 %
Total aerobic count (TAMC)	max. 2000 CFU/g	< 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g	< 200 CFU/g

Regarding the Residual Solvents we state herewith, that the controlled production, handling and storage of this material precludes the pre- sence of the organic solvents as specified in Ph.Eur. (ICH 283/95).

Heavy metal parameters of this spec. have been set in accordance to ICH Q3D guideline for elemental

The product has been tested and found in compliance with above stated parameters. Above information does, however, not release customer from making his own controls upon receipt of goods.

Dr. Paul Lohmann GmbH & Co. KGaA - Postfach 12 20 - D-31857 Emmerthal

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Parameters	Limits	Results
impurities on basis of a product related risk assessment. The risk assessment has been conducted considering option 1 (max. daily intake of 10g/d) for an oral application. Unless otherwise indicated or specified, the elements of class 1-3 (classification acc. ICH Q3D) are not likely to be present above the ICH Q3D option 1 limit in accordance to our assessment. Further elements are not intentionally added.		
The specification comprises elemental impurities based on the corresponding monograph. These elements are furthermore considered in the specification to comply with the monograph.		

Manufacturer:

Dr. Paul Lohmann GmbH & Co. KGaA, Hauptstrasse 2, D-31860 Emmerthal



(QC Manager)

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