Dr. Paul Lohmann®

High value mineral salts

Specification

Ferrous Sulfate, Dried

Powder, USP-NF 2024, FCC 14

Formula: FeSO4 * x H2O (anh.) Mol. weight: 151.90 g/mol

Parameters	Limits
Description	powder
Colour	greyish white
Identification	conforms
Insoluble substances	max. 0.05 %
Arsenic (As)	max. 0.0003 %
Lead (Pb)	max. 0.0002 %
Mercury (Hg)	max. 0.0001 %
Lead (Pb, ICH-Q3D)	max. 2.0 ppm
Cobalt (Co, ICH-Q3D)	max. 25.0 ppm
Nickel (Ni, ICH-Q3D)	max. 100.0 ppm
Vanadium (V, ICH-Q3D)	max. 50.0 ppm
Assay FeSO4	86.0-89.0 %
Total aerobic count (TAMC)	max. 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g

Regarding the Residual Solvents we state herewith, that the controlled production, handling and storage of this material precludes the presence of the organic solvents as specified in Ph.Eur. (ICH 283/95) and USP <467>.

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

This is a computer generated document and therefore does not require a signature

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Parameters	Limits
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.	

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