

SPECIFICATION**Ferrous Sulfate, Dried**

Powder, USP 43

Formula: $\text{FeSO}_4 \cdot x \text{H}_2\text{O}$

Mol. weight: 151.9 (anhydrous)

Parameters	Limits
Description	Powder
Colour	Greyish white
Identification	conforms
Insoluble substances	max. 0.05 %
Arsenic (As)	max. 0.0003 %
Lead (Pb)	max. 0.001 %
Mercury (Hg)	max. 0.0003 %
Lead (Pb, ICH-Q3D)	max. 10 ppm
Cobalt (Co, ICH-Q3D)	max. 25 ppm
Nickel (Ni, ICH-Q3D)	max. 150 ppm
Vanadium (V, ICH-Q3D)	max. 100 ppm
Assay FeSO_4	86.0-89.0 %
Total aerobic count (TAMC)	max. 1000 CFU/g
Yeasts and moulds (TYMC)	max. 100 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 specification 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.

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.