

## **Specification**

## 1.28209.0000 Zinc sulfate heptahydrate EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP

	Spec. Values	
Appearance	white or colorless crystals or crystalline powder	
Assay (complexometric)	99.0 – 102.0	%
Identity	passes test	
Appearance of solution	passes test	
Free acid	passes test	
pH-value (5 %; water)	4.4 – 5.6	
Chloride (CI)	≤ 0.0005	%
Heavy metals	≤ 0.0010	%
As (Arsenic)	≤ 0.0001	%
Cd (Cadmium) (*)	≤ 0.0002	%
Fe (Iron)	≤ 0.001	%
Hg (Mercury)	≤ 0.0005	%
Ni (Nickel) (*)	≤ 0.0005	%
Pb (Lead)	≤ 0.0004	%
Se (Selenium)	≤ 0.003	%
TI (Thallium)	≤ 0.0002	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Alkali- and alkaline earth metals (as SO <sub>4</sub> )	≤ 0.5	%
Loss on drying (105 °C)	35.5 – 38.5	%

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (\*). Corresponds to Ph Eur,BP,ChP,JP,USP

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