

Specification

1.28209.0000	Zinc sulfate heptahydrate EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP
1.20200.0000	

	Spec. Values	
Appearance	white or colorless crystals or crystalline powder	
Assay (complexometric)	99.0 – 102.0	%
Assay (USP)	99.0 – 108.7	%
Identity	passes test	
Identity (USP)	passes test	
Appearance of solution	passes test	
Free acid	passes test	
pH-value (5 %; water)	4.4 – 5.6	
Chloride (Cl)	≤ 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 SO4)	≤ 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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Responsible laboratory quality control			
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