

## Certificate of Analysis

**Product name:** **Zinci sulfas heptahydricus**

**Batch number / Weight:** **22K28-B10-229431 / 50 G**

**Analysed according to:** **Ph.Eur.11**

**Number of analysis / Inspection Code** **22K28-B10 / INS-22-9999**

**Reference Code / No.:** **V00225 / ZSH 0182**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost)White, crystalline powder or colourless,	Conform		
	transparent crystals, efflorescent			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Solubility in water	very soluble in water	Conform		
Solubility in alcohol	practically insoluble in ethanol (96%)	Conform		
Appearance of solution	Clear / Colourless	Conform		
pH	4,4 - 5,6	5,12		
Chlorides	<=300	Conform	ppm	
Iron	<=100	Conform	ppm	
Assay	99,0 - 104,0	100,04	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Total aerobic microbial count (TA)	<=10 <sup>2</sup>	<1	CFU/g	
Total yeasts and moulds (TYMC)	<=10 <sup>1</sup>	<1	CFU/g	
Pseudomonas aeruginosa	Absent in 1 g	Conform		
Staphylococcus aureus	Absent in 1 g	Conform		
Candida albicans	Absent in 1 g	Conform		
Escherichia coli	Absent in 1 g	Conform		

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:  
Dominika Soltysik  
Qualified Person

12-05-2023

Expiration: 10-10-2025

Conclusion: APPROVED

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