

## Certificate of Analysis

**Product name:** **Dinatrii edetas**

**Batch number / Weight:** **21L06-B01-217313 / 10 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,0 - 5,5	4,43		
Related substances	$\leq 0,1$	0,01	%	
Iron	$\leq 80$	Conform	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	98,9	%m/m	
Total aerobic microbial count (TA)	$\leq 10^3$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Ewelina Gadzinowska  
Qualified Person

15-03-2022

Expiration: 31-08-2024

Conclusion: APPROVED

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