

## Certificate of Analysis

**Product name:** **Chlortalidonum**  
**Batch number / Weight:** **21G13-B16-213520 / 10 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder	Conform		
Identification A	Conform	Conform		
Acidity	$\leq 0,75$ ml NaOH 0.1M	0,15 ml		
Related substances	Conform	Conform		
Impurity B	$\leq 0,7$	$< 0,05$	%	
Impurity G	$\leq 0,2$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 1,2$	$< 0,05$	%	
Chlorides	$\leq 350$	$< 350$	ppm	
Loss on drying	$\leq 0,5$	0,05	%	
Sulphated ash	$\leq 0,1$	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chlortalidone	97,0 - 102,0	100,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

22-11-2021

Expiration: 31-08-2025

Conclusion: APPROVED

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