

## Certificate of Analysis

**Productname:** **Chlortalidonum**  
**Number of analysis/Inspection Code:** 1 / KEUR-187928B  
**Batchnumber:** **20A13-F03-373443**  
**Reference code / No.:** 1250 / 3079/90420  
**Analysed according to:** **PH.EUR10.0**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder	Conform		
Identification	Conform	Conform		IR-spectrum
Acidity	<=0,75 ml NaOH 0.1M	Conform		
Related substances	Conform	Conform		HPLC
Impurity B	<=0,7	<0,05	%	
Impurity G	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,2	<0,05	%	
Chlorides	<=350	Conform	ppm	
Loss on drying	<=0,5	0,2	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Chlortalidone	97,0 - 102,0	99,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

12/28/20

Expiration: 06-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.