

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

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