

Certificate of Analysis

Productname: Disulfiramum
Number of analysis/Inspection Code: 1 / KEUR-176959B
Batchnumber: 19E29-B01-362885
Reference code / No.: 4539 / API-137/19/05/01
Analysed according to: PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	70 - 73	72	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Related substances	<=0,5	Conform	%	TLC
Diethyldithiocarbamate	<=150	Conform	ppm	
Loss on drying	<=0,5	0,1	%	50°C vacuum
Sulphated ash	<=0,1	0,1	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Disulfiram	98,5 - 101,0	100,7	%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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

10/11/19

Expiration: 05-2024

Conclusion: APPROVED

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