

Certificate of Analysis

Productname: Disulfiramum
Number of analysis/Inspection Code: 1 / KEUR-184292B
Batchnumber: 20F18-F03-371712
Reference code / No.: 4539 / API-137/20/03/02
Analysed according to: PH.EUR10.2

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | 70 - 73 | 71 | °C | Melting point |
| Identification B | Conform | Conform | | IR-spectrum |
| Related substances | <=0,5 | Conform | % | TLC |
| Diethyldithiocarbamate | <=150 | Conform | ppm | |
| Loss on drying | <=0,5 | 0,0 | % | 50°C vacuum |
| Sulphated ash | <=0,1 | 0,0 | % | |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Assay Disulfiram | 98,5 - 101,0 | 100,3 | %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

07/16/20

Expiration: 03-2025

Conclusion: APPROVED

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