

Certificate of Analysis

Productname: Melatoninum
Number of analysis/Inspection Code: 1 / KEUR-180697B
Batchnumber: 20A15-F03-367975
Reference code / No.: 3848 / MLT/519021
Analysed according to: BP2019

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------|--|---------|------|-----------------|
| Appearance | (Almost) white crystalline powder | Conform | | |
| Identification | Conform | Conform | | IR-spectrum |
| Related substances | Conform | Conform | | HPLC |
| 5-Methoxytryptamine | <=0,5 | <0,01 | % | |
| Any secondary peak | <=0,1 | <0,05 | % | |
| Total impurities | <=1,0 | <0,05 | % | |
| Water | <=0,3 | 0,0 | % | Karl Fischer |
| 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 Melatonin | 98,0 - 102,0 | 100,8 | %m/m | Anhydrous |
| 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

02/25/20

Expiration: 05-2024

Conclusion: APPROVED

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