

Certificate of Analysis

Product name: **Tacrolimus monohydricus**
Batch number / Weight: **21I24-B12-215835 / 500 MG**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white powder | Conform | | |
| Identification | Conform | Conform | | |
| Appearance of solution | Conform | Conform | | |
| Particle size | 100%≤100 µm | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | ≤0,5 | <0,05 | | |
| Any other impurity | ≤0,15 | <0,05 | % | |
| Total impurities | ≤1,0 | <0,05 | % | |
| Water (Karl Fischer) | 1,5 - 4,0 | 1,88 | % | |
| Sulphated ash | ≤0,1 | 0,09 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Tacrolimus | 97,0 - 102,0 | 99,4 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
 Agnieszka Pszczółka
 Qualified Person

14-03-2022

Expiration: 31-01-2024

Conclusion: APPROVED

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