

Certificate of Analysis

Product name: **Amitriptylini hydrochloridum**

Batch number / Weight: **22B10-B04-218130 / 25 G**

Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|---|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder / crystals | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Appearance of solution | Clear / <B7 | Conform | | |
| Acidity or alkalinity | Conform | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity B | <=0,1 | <0,05 | % | |
| Impurity A | <=0,05 | <0,01 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=0,3 | <0,05 | % | |
| Loss on drying | <=0,5 | 0,04 | % | |
| Sulphated ash | <=0,1 | 0,07 | % | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| Acetone | <=500 ppm | 57 | ppm | |
| Tetrahydrofurane | <=500 ppm | <25 | | |
| Toluene | <= 500 ppm | 68 | ppm | |
| Assay | 99,0 - 101,0 | 100,8 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

18-05-2022

Expiration: 12-10-2026

Conclusion: APPROVED

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