

## Certificate of Analysis

**Product name:** **Amitriptylini hydrochloridum**

**Batch number / Weight:** **22F28-B04-222299 / 25 G**

**Analysed according to:** **Ph. Eur. 10.8**

| 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     | ppm  |                 |
| 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

18-08-2022

Expiration: 12-10-2026

Conclusion: APPROVED

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