

## Certificate of Analysis

**Product name:** **Amifampridinum**

**Batch number / Weight:** **22A22-B07-223737 / 5 G**

**Analysed according to:** **Monograph**

**Number of analysis / Inspection Code** **22A22-B07 / INS-22-3073**

**Reference Code / No.:** **V01521 / 33-21-II-36P4709**

| Tests                  | Requirement                                  | Result   | Unit | Standard remark |
|------------------------|--|----------|------|-----------------|
| Appearance             | White or light brown, crystalline powder     | Conform  |      |                 |
| Identification B       | Conform                                      | Conform  |      |                 |
| Appearance of solution | Clear / $\leq B5$                            | Conform  |      |                 |
| Related substances     | Conform                                      | Conform  |      |                 |
| Impurity A             | $\leq 0,1$                                   | $< 0,01$ | %    |                 |
| Any other impurity     | $\leq 0,10$                                  | $< 0,05$ | %    |                 |
| Total impurities       | $\leq 0,5$                                   | $< 0,05$ | %    |                 |
| Water (Karl Fischer)   | $\leq 1,0$                                   | 0,10     | %    |                 |
| Sulphated ash          | $\leq 0,1$                                   | 0,08     | %    |                 |
| Metallic residues      | CHMP/ICH/353369/2013                         | Conform  |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06                           | Conform  |      | Data producer   |
| Assay Amifampridin     | 99,0 - 101,0                                 | 100,5    | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform  |      | Data producer   |
| Residual solvents      |  |          |      |                 |
| Methanol               | not more than 1500 ppm                       | 72       | ppm  |                 |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

27-09-2022

Expiration: 13-12-2024

Conclusion: APPROVED

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