

Certificate of Analysis

Product name: **Carbamazepinum**
Batch number / Weight: **21J13-B08-217686 / 50 G**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | | Conform | | |
| Identification A | | 191,5 | °C | |
| Identification B | | Conform | | |
| Acidity or alkalinity | | Conform | | |
| Related substances | | Conform | | |
| Impurity A | | 0,06 | % | |
| Impurity E | | <0,05 | % | |
| Unspecified impurities | | <0,05 | % | |
| Total impurities | | 0,06 | % | |
| Chlorides | | <140 | ppm | |
| Loss on drying | | 0,03 | % | |
| Sulphated ash | | 0,01 | % | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | | 100,38 | %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:
Dominika Sołtysik
Qualified Person

09-04-2022

Expiration: 31-08-2024

Conclusion: APPROVED

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