

## Certificate of Analysis

**Product name:** **Carbamazepinum**

**Batch number / Weight:** **23J02-B04-233007 / 50 G**

**Analysed according to:** **Ph.Eur.11.2**

**Number of analysis / Inspection Code** **23J02-B04 / INS-23-8243**

**Reference Code / No.:** **V00375 / 101042328**

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance             | (Almost) white, crystalline powder           | Conform |      |                 |
| Identification A       | 189 - 193                                    | 192,1   | °C   |                 |
| Identification B       | Conform                                      | Conform |      |                 |
| Acidity or alkalinity  | Conform                                      | Conform |      |                 |
| Related substances     | Conform                                      | Conform |      |                 |
| Impurity A             | <=0,15                                       | <0,05   | %    |                 |
| Impurity E             | <=0,15                                       | <0,05   | %    |                 |
| Unspecified impurities | <=0,10                                       | <0,05   | %    |                 |
| Total impurities       | <=0,5  | <0,05   | %    |                 |
| Chlorides              | <=140  | <140    | ppm  |                 |
| Loss on drying         | <=0,5  | 0,09    | %    |                 |
| Sulphated ash          | <=0,1  | 0,02    | %    |                 |
| Residual solvents      | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay                  | 98,0 - 102,0                                 | 99,55   | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Metallic residues      | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |

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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 Fagron PL, EI Spol

Release:

Ewelina Gadzinowska

Qualified Person

14-12-2023

Expiration: 30-04-2026

Conclusion: APPROVED

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