

## Certificate of Analysis

**Product name:** **Prednisonum micronisatum**

**Batch number / Weight:** **23A04-B03-228578 / 25 G**

**Analysed according to:** **Ph.Eur.11**

**Number of analysis / Inspection Code** **23A04-B03 / INS-23-0576**

**Reference Code / No.:** **V00619 / NUPD 221003**

| Tests                     | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance                | (almost) white, crystalline powder           | Conform |      |                 |
| Particle size             | 99% < 25 µm / 90% < 10 µm                    | Conform |      |                 |
| Identification A          | Conform                                      | Conform |      |                 |
| Identification C          | Conform                                      | Conform |      |                 |
| Specific optical rotation | +183 - +191                                  | +187,8  |      |                 |
| Related substances        | Conform                                      | Conform |      |                 |
| Impurity A                | <=0,5  | 0,15    | %    |                 |
| Impurity E                | <=0,2  | <0,05   | %    |                 |
| Impurity D                | <=0,15                                       | 0,000   | %    |                 |
| Unspecified impurities    | <=0,10                                       | 0,069   | %    |                 |
| Total impurities          | <=1,0  | 0,34    | %    |                 |
| Loss on drying            | <=1,0  | 0,00    | %    |                 |
| Metallic residues         | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents         | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay                     | 97,0 - 102,0                                 | 98,26   | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Residual solvents         |  |         |      |                 |
| Acetone                   | <5000 ppm                                    | <5000   | 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 Fagron PL lab,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

31-05-2023

Expiration: 02-08-2024

Conclusion: APPROVED

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