

## Certificate of Analysis

**Product name:** **Dexamethasonum micronisatum**

**Batch number / Weight:** **23I11-B11-236004 / 5 G**

**Analysed according to:** **Ph.Eur.11.3**

**Number of analysis / Inspection Code** **23I11-B11 / INS-23-7332**

**Reference Code / No.:** **V00619 / NUD230501-1**

| 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 B          | Conform                                      | Conform |      |                 |
| Specific optical rotation | +86 - +92                                    | +90,0   |      |                 |
| Related substances        | Conform                                      | Conform |      |                 |
| Impurity G                | <=0,3  | <0,05   | %    |                 |
| Impurity B                | <=0,15                                       | <0,05   | %    |                 |
| Impurity F                | <=0,15                                       | <0,05   | %    |                 |
| Impurity J                | <=0,15                                       | <0,05   | %    |                 |
| Impurity K                | <=0,15                                       | <0,05   | %    |                 |
| Unspecified impurities    | <=0,10                                       | <0,05   | %    |                 |
| Total impurities          | <=0,5  | 0,00    | %    |                 |
| Loss on drying            | <=0,5  | 0,15    | %    |                 |
| Metallic residues         | CHMP/ICH/353369/2013                         | Conform |      |                 |
| Residual solvents         | CPMP/ICH/82 260/06                           | Conform |      |                 |
| Assay                     | 97,0 - 103,0                                 | 100,01  | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      |                 |

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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

Release:  
Dominika Soltysik  
Qualified Person

19-01-2024

Expiration: 08-04-2027

Conclusion: APPROVED

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