

## Certificate of Analysis

**Product name:** **Hydrocortisonum micronisatum**

**Batch number / Weight:** **22J19-B02-226690 / 5 G**

**Analysed according to:** **Ph.Eur.11.0**

**Number of analysis / Inspection Code** **22J19-B02 / INS-22-8817**

**Reference Code / No.:** **V00603 / K05M20211101M**

| Tests                     | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance                | Fine, (almost) white powder                  | Conform |      |                 |
| Particle size             | 99% < 25 µm / 90% < 10 µm                    | Conform |      |                 |
| Identification A          | Conform                                      | Conform |      |                 |
| Identification B          | Conform                                      | Conform |      |                 |
| Identification            | Conform                                      | Conform |      |                 |
| Specific optical rotation | +162 - +168 (dried substance)                | +163,2  |      |                 |
| Related substances        | Conform                                      | Conform |      |                 |
| Impurity C                | <=0,5  | <0,05   | %    |                 |
| Impurity D                | <=0,5  | <0,05   | %    |                 |
| Impurity E                | <=0,5  | <0,05   | %    |                 |
| Impurity I                | <=0,5  | <0,05   | %    |                 |
| Impurity G                | <=0,4  | 0,09    | %    |                 |
| Impurity F                | <=0,3  | <0,05   | %    |                 |
| Impurity A                | <=0,2  | 0,06    | %    |                 |
| Impurity B                | <=0,2  | <0,05   | %    |                 |
| Impurity H                | <=0,15                                       | 0,000   | %    |                 |
| Impurity N                | <=0,15                                       | 0,059   | %    |                 |
| Unspecified impurities    | <=0,10                                       | 0,073   | %    |                 |
| Total impurities          | <=2,0  | 0,33    | %    |                 |
| Loss on drying            | <=1,0  | 0,07    | %    |                 |
| Metallic residues         | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents         | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay                     | 97,0 - 103,0 (dried substance)               | 101,17  | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Residual solvents         |  |         |      |                 |
| Methanol                  | <=3000                                       | <3000   | ppm  |                 |
| Acetone                   | <=5000                                       | <5000   | ppm  |                 |

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|                 |               |         |     |
|-----------------|---------------|---------|-----|
| Dichloromethane | <=600         | <600    | ppm |
| Acetic acid     | <= 0,5% (LOD) | Conform |     |

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, ElSpol

Release:

Ewelina Gadzinowska

Qualified Person

19-01-2023

Expiration: 31-10-2026

Conclusion: APPROVED

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