

## Certificate of Analysis

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

**Batch number / Weight:** **22E09-B04-225275 / 25 G**

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

**Number of analysis / Inspection Code** **22E09-B04 / INS-22-4179**

**Reference Code / No.:** **V00603 / K05M20210104M**

| 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)                | +165,5  |      |                 |
| Related substances        | Conform                                      | Conform |      |                 |
| Impurity C                | <=0,5  | 0,07    | %    |                 |
| 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  | <0,05   | %    |                 |
| Impurity B                | <=0,2  | <0,05   | %    |                 |
| Impurity H                | <=0,15                                       | <0,05   | %    |                 |
| Impurity N                | <=0,15                                       | 0,053   | %    |                 |
| Unspecified impurities    | <=0,10                                       | 0,046   | %    |                 |
| Total impurities          | <=2,0  | 0,31    | %    |                 |
| Loss on drying            | <=1,0  | 0,01    | %    |                 |
| 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)               | 100,31  | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Residual solvents         |  |         |      |                 |
| Acetone                   | not more than 3000 ppm                       | 925     | ppm  |                 |
| Methanol                  | not more than 1500 ppm                       | <30     | ppm  |                 |

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Dichloromethane

not more than 100 ppm

<30

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

25-11-2022

Expiration: 31-12-2025

Conclusion: APPROVED

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