

Certificate of Analysis

Product name: **Hydrocortisonum micronisatum**
Batch number / Weight: **19K05-B02-195621 / 25 G**
Analysed according to: **Ph. Eur.**

| 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 | | |
| Specific optical rotation | +162 - +168 | +164,5 | ° | |
| Related substances | Conform | Conform | | |
| Impurity C | <=0,5 | <0,05 | % | |
| Impurity D | <=0,5 | 0,34 | % | |
| Impurity E | <=0,5 | 0,07 | % | |
| Impurity I | <=0,5 | 0,16 | % | |
| Impurity G | <=0,4 | <0,05 | % | |
| Impurity F | <=0,3 | <0,05 | % | |
| Impurity A | <=0,2 | 0,13 | % | |
| Impurity B | <=0,2 | <0,05 | % | |
| Impurity H | <=0,15 | <0,05 | % | |
| Impurity N | <=0,15 | 0,00 | % | |
| Unspecified impurities | <=0,10 | 0,09 | % | |
| Total impurities | <=2,0 | 0,79 | % | |
| Loss on drying | <=1,0 | 0,13 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 97,0 - 103,0 | 100,58 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

29-01-2020

Expiration: 13-06-2022

Conclusion: APPROVED

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