

Certificate of Analysis

Product name: **Fludrocortisoni acetat micr.**

Batch number / Weight: **22A14-B03-216763 / 300 MG**

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

| 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 | +148 - +156 | +151,3 | | |
| Related substances | Conform | Conform | | |
| Any impurity | <=1,0 | 0,13 | % | |
| Total impurities | <=1,5 | 0,34 | % | |
| 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 Fludrocortisone acetate | 97,0 - 103,0 | 98,65 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Residual solvents | | | | |
| Methanol | not more than 1500 ppm | <3000 | ppm | |
| Ethanol | not more than 2000 ppm | <5000 | ppm | |
| Dichloromethane | | 0,0 | ppm | |
| Ethyl acetate | <= 5000 | <5000 | ppm | |
| Tetrahydrofurane | | <720 | ppm | |
| Pyridine | | 0,0 | ppm | |
| Dimethylformamide | <880 ppm | 0,0 | ppm | |

Analysis performed by the authorized lab.

Release:
Dominika Soltysik
Qualified Person

28-04-2022

Expiration: 31-01-2025

Conclusion: APPROVED

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