

Certificate of Analysis

Product name: **Diflucortoloni valeras micron.**

Batch number / Weight: **22A20-B01-219524 / 1 G**

Analysed according to: **BP**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------|--|---------|------|-----------------|
| Appearance | Fine, (almost) white powder | Conform | | |
| Particle size | 99% <20 µm / 95% <10 µm | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Specific optical rotation | +98 - +103 | +103 | | |
| Related substances | Conform | Conform | | |
| Any impurity | <=1 | 0,25 | % | |
| Total impurities | <=2 | 0,41 | % | |
| Loss on drying | <=0,5 | 0,04 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| Assay Diflucortolon valerate | 97,0 - 102,0 | 99,7 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |
| Residual solvents | | | | |
| Methanol | <=3000 | <25 | ppm | |
| Ethanol | not more than 2000 ppm | <25 | ppm | |
| Acetone | not more than 3000 ppm | <25 | ppm | |
| Methylene chloride | <=600 | 11 | ppm | |
| Tetrahydrofurane | | <25 | ppm | |
| Isopropyl ether | <=200 | <4 | ppm | |
| Isopropenyl acetate | <=200 | <4 | ppm | |
| Methyl isobuthyl ketone | <=2000 | <40 | ppm | |
| Pyridine | | <4 | ppm | |
| Dimethylformamide | <880 ppm | <15 | ppm | |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

27-05-2022

Expiration: 30-04-2026

Conclusion: APPROVED

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