

Certificate of Analysis

Product name: **Betamethasoni valeras micr.**
Batch number / Weight: **21K09-B05-216144 / 1 G**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------|--|---------|------|-----------------|
| Appearance | Fine, (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 | +77 - +83 | +78,3 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,7 | <0,05 | % | |
| Impurity C | <=0,15 | <0,05 | % | |
| Impurity E | <=0,3 | 0,11 | % | |
| Impurity G | <=0,3 | <0,05 | % | |
| Impurity H | <=0,15 | <0,05 | % | |
| Impurity I | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | 0,074 | % | |
| Total impurities | <=1,5 | 0,18 | % | |
| Loss on drying | <=0,5 | 0,03 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Betamethasone valerate | 97,0 - 103,0 | 100,39 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

30-03-2022

Expiration: 30-06-2026

Conclusion: APPROVED

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