

## Certificate of Analysis

**Product name:** **Betamethasonum**  
**Batch number / Weight:** **21K15-B08-213812 / 1 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                      | Requirement                                  | Result   | Unit | Standard remark |
|----------------------------|--|----------|------|-----------------|
| Appearance                 | Fine, (almost) white powder                  | Conform  |      |                 |
| Particle size              | 99% <25 µm and 90% <10 µm                    | Conform  |      |                 |
| Identification B           | Conform                                      | Conform  |      |                 |
| Identification C           | Conform                                      | Conform  |      |                 |
| Specific optical rotation  | +118 - +126                                  | +121     | °    |                 |
| Related substances         | Conform                                      | Conform  |      |                 |
| Impurity A                 | <=1,0  | <0,05    | %    |                 |
| Impurity B                 | <=1,0  | <0,05    | %    |                 |
| Impurity C                 | <=1,0  | <0,05    | %    |                 |
| Impurity D                 | <=1,0  | <0,05    | %    |                 |
| Impurity E                 | <=1,0  | <0,05    | %    |                 |
| Impurity F                 | <=1,0  | <0,05    | %    |                 |
| Impurity G                 | <=1,0  | <0,05    | %    |                 |
| Impurity H                 | <=1,0  | <0,05    | %    |                 |
| Impurity I                 | <=1,0  | <0,05    | %    |                 |
| Impurity J                 | <=1,0  | <0,05    | %    |                 |
| Impurity A to J            | Max. 1 peak >=0,5                            | max.0,08 | %    |                 |
| Total impurities           | <=2,0  | 0,20     | %    |                 |
| Loss on drying             | <=0,5  | 0,13     | %    |                 |
| Metallic residues          | CHMP/ICH/353369/2013                         | Conform  |      | Data producer   |
| Residual solvents          | CPMP/ICH/82 260/06                           | Conform  |      | Data producer   |
| Assay Betamethasone (base) | 97,0 - 103,0                                 | 99,6     | %m/m |                 |
| TSE/BSE-statement:         | No contamination with TSE/BSE-risk materials | Conform  |      | Data producer   |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-02-2022

Expiration: 24-06-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.