

Certificate of Analysis

Product name: **Betamethasoni dipropionas micr**

Batch number / Weight: **21K24-B04-226858 / 5 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **21K24-B04 / INS-22-1600**

Reference Code / No.: **V01236 / BDP 004/0821**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | White or almost white, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Particle size | 99% < 25 µm / 90% < 10 µm | Conform | | |
| Specific optical rotation | + 84 - + 88 | +86,8 | | |
| Related substances | Conform | Conform | | |
| Impurity C | <=0,5 | 0,13 | % | |
| Impurity B | <=0,3 | <0,05 | % | |
| Impurity H | <=0,3 | <0,05 | % | |
| Impurity D | <=0,2 | <0,05 | % | |
| Impurity E | <=0,2 | <0,05 | % | |
| Impurity G | <=0,2 | <0,05 | % | |
| Impurity I | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | 0,084 | % | |
| Total impurities | <=1,0 | 0,29 | % | |
| Loss on drying | <=1,0 | 0,17 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 97,0 - 102,0 | 99,82 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

16-01-2023

Expiration: 31-07-2026

Conclusion: APPROVED

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