

Certificate of Analysis

Product name: **Betamethasoni dipropionas micr**

Batch number / Weight: **23F20-B02-233808 / 5 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23F20-B02 / INS-23-5382**

Reference Code / No.: **V01236 / BDP 003/0223**

| 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 | 85,6 | | |
| Related substances | Conform | Conform | | |
| Impurity C | <=0,5 | 0,19 | % | |
| 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 | 0,047 | % | |
| Unspecified impurities | <=0,10 | 0,074 | % | |
| Total impurities | <=1,0 | 0,31 | % | |
| Loss on drying | <=1,0 | 0,36 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 97,0 - 102,0 | 99,70 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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:
Dominika Soltysik
Qualified Person

16-10-2023

Expiration: 31-01-2028

Conclusion: APPROVED

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

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl