

Certificate of Analysis

Product name: **Hydrocortisoni acetat micr.**

Batch number / Weight: **23E18-B03-238564 / 1 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23E18-B03 / INS-23-4076**

Reference Code / No.: **V01235 / HD0125**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | (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 | +158 - +167 | +163,5 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,5 | 0,19 | % | |
| Impurity B | <=0,3 | <0,05 | % | |
| Impurity C | <=0,6 | 0,06 | % | |
| Impurity D | <=0,3 | <0,05 | % | |
| Impurity E | <=0,3 | <0,05 | % | |
| Impurity G | <=0,15 | 0,000 | % | |
| Unspecified impurities | <=0,10 | 0,059 | % | |
| Total impurities | <=1,5 | 0,31 | % | |
| Loss on drying | <=0,5 | 0,05 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 97,0 - 102,0 | 99,34 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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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,CBMiA

Release:
Dominika Soltysik
Qualified Person

29-03-2024

Expiration: 14-08-2025

Conclusion: APPROVED

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