

Certificate of Analysis

Product name: **Methylprednisolonum micr.**

Batch number / Weight: **22D14-B07-222966 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22D14-B07 / INS-22-4224**

Reference Code / No.: **V00619 / NXEMP211209-1**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | Fine, (almost) white powder | Conform | | |
| Particle size | 99% < 25 µm / 90% < 10 µm | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Specific optical rotation | +97,0 - +103,0 | +97,1 | | |
| Related substances | Conform | Conform | | |
| Impurity D | <=0,5 | <0,05 | % | |
| Impurity A | <=0,3 | 0,06 | % | |
| Impurity G and I | <=0,3 | 0,00 | % | |
| Impurity H | <=0,2 | <0,05 | % | |
| Impurity B | <=0,2 | <0,05 | % | |
| Impurity C | <=0,15 | <0,05 | % | |
| Impurity E | <=0,15 | 0,00 | % | |
| Impurity F | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | 0,053 | % | |
| Total impurities | <=2,0 | 0,16 | % | |
| Loss on drying | <=1,0 | 0,30 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Methylprednisolone | 97,0 - 102,0 | 100,10 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Residual solvents | | | | |
| Methanol | <= 3000 | <3000 | ppm | |
| Dichloromethane | <= 600 | <600 | ppm | |
| Chloroform | <= 60 | <60 | ppm | |

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@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:
Ewelina Gadzinowska
Qualified Person

18-10-2022

Expiration: 30-11-2025

Conclusion: APPROVED

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

fagron.pl

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