



## **Certificate of Analysis**

Product name: Finasteridum

Batch number / Weight: 24D08-B03 / KG

Analysed according to: Ph.Eur. 01/2014:1615

Number of analysis / Inspection Code /

Reference Code / No.: V01757 / FSD-240104

| Tests                     | Requirement                       | Result     | Unit | Standard remark |
|---------------------------|-----------------------------------|------------|------|-----------------|
|                           |                                   | 898/S/0424 |      |                 |
| Appearance                | (Almost) white crystalline powder | Conform    |      |                 |
| Identification            | Conform                           | Conform    |      |                 |
| Specific optical rotation | +12,0 - +14,0                     | +13,1      |      |                 |
| Related substances        | Conform                           | Conform    |      |                 |
| Impurity A                | <=0,3                             | 0,10       | %    |                 |
| Impurity C                | <=0,3                             | <0,05      | %    |                 |
| Any other impurity        | <=0,10                            | <0,05      | %    |                 |
| Total impurities          | <=0,5                             | 0,10       | %    |                 |
| Loss on drying            | <=0,5                             | 0,09       | %    |                 |
| Assay Finasteride         | 98,0 - 102,0                      | 99,10      | %m/m |                 |
| Residual solvents:        |                                   | 1,010      |      |                 |

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 Own lab

Release:

Daria Berkowicz

**Quality Control Specialyst** 

17-04-2024

Expiration: 17-01-2029

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

fagron.pl Fagron sp. z o.o.

ul. Pasternik 26, 31-354 Kraków, Poland

tel.: +48 12 3343 512 e-mail: biuro@fagron.pl