

## **Certificate of Analysis**

Product name: Minoxidilum

Batch number / Weight: 23D27-B04-232263 / 10 G

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 23D27-B04 / INS-23-3822

Reference Code / No.: V01120 / 23002

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance             | (Almost) white, crystalline powder           | Conform |      |                 |
| Identification B       | Conform                                      | Conform |      |                 |
| Related substances     | Conform                                      | Conform |      |                 |
| Impurity E             | <=0,2  | 0,058   | %    |                 |
| Impurity B             | <=0,15                                       | 0,000   | %    |                 |
| Unspecified impurities | <=0,10                                       | <0,05   | %    |                 |
| Total impurities       | <=0,3  | 0,06    | %    |                 |
| Loss on drying         | <=0,5  | 0,05    | %    |                 |
| Sulfated ash           | <=0,1  | 0,06    | %    |                 |
| Assay Minoxidil        | 99,0 - 101,0 (dried substance)               | 99,95   | %m/m |                 |
| Metallic residues      | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

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:

Agnieszka Pszczółka Qualified Person

19-09-2023

Expiration: 31-03-2028

Conclusion: APPROVED

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