

## Certificate of Analysis

**Product name:** **Miconazoli nitras**

**Batch number / Weight:** **23G31-B07-233012 / 3 G**

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

**Number of analysis / Inspection Code** **23G31-B07 / INS-23-6276**

**Reference Code / No.:** **V01872 / MIMA3325**

| Tests                    | Requirement                                  | Result  | Unit | Standard remark |
|--------------------------|--|---------|------|-----------------|
| Appearance               | (Almost) white powder                        | Conform |      |                 |
| Particle size            | 99%<25 µm / 90%<10 µm                        | Conform |      |                 |
| Identification A         | Conform                                      | Conform |      |                 |
| Identification B         | Conform                                      | Conform |      |                 |
| Appearance of solution   | Clear <=Y7                                   | Conform |      |                 |
| Optical rotation         | -0,10 - +0,10                                | -0,001  | °    |                 |
| Related substances       | Conform                                      | Conform |      |                 |
| Impurity C               | <=0,2  | 0,00    | %    |                 |
| Sum impurities F and G   | <=0,2  | 0,06    | %    |                 |
| Unspecified impurities   | <=0,10                                       | <0,05   | %    |                 |
| Total impurities         | <=0,5  | 0,06    | %    |                 |
| Loss on drying           | <=0,5  | 0,06    | %    |                 |
| Sulphated ash            | <=0,1  | 0,03    | %    |                 |
| 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   |
| Assay Miconazole nitrate | 99,0 - 101,0 (dried substance)               | 100,50  | %m/m |                 |

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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

22-09-2023

Expiration: 31-05-2028

Conclusion: APPROVED

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